EPA Jacket 2382-189

Material Sent for Data Extraction

| Reg # _ 2382- KIO |
|--|
| Description: Product Registration |
| ☐ Material(s) Sent to Data Extraction Contractors: |
| New Stamped Label Dated 7-6-12 |
| Notification Dated |
| ☐ New CSF(s) Dated |
| ☐ Other: |
| ☐ Decision #: |
| ☐ Other Action/Comments: |
| |
| Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900). Reviewer: REGINA FOUSHEE-Smith |
| • |
| Phone: 65-6180 Division: RD |
| Date: |

ENVIRONMENTAL PROTECTION AGENCY EPA Registration No. Date of Issuance: Office of Posticide Programs Registration Division (7505P) July 6, 2012 1200 Pennsylvania Ave., N.W. 2382-189 Washington, D.C. 20460 Term of issuance: NOTICE OF PESTICIDE: Unconditional ☑ Registration ☐ Reregistration (under the Federal Insecticide, Fungicide, and Rodenticide Act, as Name of Pesticide Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS amended) Name and Address of Registrant (include ZIP Code): Virbac Animal Health, Inc. P.O. Box 162059 Fort Worth, TX 76161 Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number. On the basis of information furnished by the registrant, the above named posticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This action is taken under the authority of section 3(e)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of posticides. EPA may require submission of data at any time to maintain the registration of your product. Terms of Registration 1. EPA has registered the product listed above provided that the following change is made to the label before you release the product for shipment: Revise the EPA Registration Number to read: "EPA Registration No 2382-189." 2. The Net Contents must be displayed in accordance with the description identified in the Labeling Consistency Committee's clarification. This information may be located at the following Agency web site under miscellaneous http://www.epa.gov/opp00001/regulating/labels/label_review_fag.litm#miscellaneous.

Signature of Approving Official:

Refer to Page 3

July 6, 2012

Richard J. Gebken, Product Manager (10)
Registration Division, Insecticide Branch

"Regarding listing net contents - Net weight or contents must be stated on a pesticide label in accordance with FIFRA (2)(q)(2)(C)(iii) and 40 CFR 156.I0(a)(1)(iii). EPA interpretation of the statutory and regulatory requirements is that the label must state the total weight for the entire contents as sold and distributed. In

EPA Form 8570-6

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addition, the label may indicate the net weight and quantity of individual units within the carton. For example, "Net Weight 6.25 lbs. (20 - 5oz. packets)." For additional information regarding the Net Weight/Contents statement, please reference Chapter 17 of the Label Review Manual at http://www.epa.gov/oppfead1/labeling/lrm/chap-17.htm."

- 3. This registration is time-limited and expires two years from the date this product is first released for shipment. You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.
- 4. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient).
- You must submit the following data within the timeframe described below:
 Within sixteen (16) months of the date on this Notice of Registration, provide to the Agency acceptable data
 packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage
 Stability).
- 6. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on August 1, 2012. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number

Product name (brand name)

Lot#

Where purchased: internet, store, Veterinarian

Active Ingredient(s)

Weight range for product

Date on which incident occurred, (mm/dd/yyyy)

State in which the incident occurred, (standard 2 letter abbreviation)

Registrant case #

Species: dog, cat, other (specify)

Breed: (as reported by pet owner)

Age: months or years Sex: M, F, or neutered

Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other

Body System: neurological, dermatological, Gl, respiratory, ocular, other Major signs noted

Time to Onset: (hours, days)
Treated by veterinarian; yes or no
First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor Outcome: died, recovered, still treated, unknown

- 7. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
 - a. All minor dermal and ocular irritation reports.
 - b. Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for dogs and table for cats showing number of incidents that are believed due to

Page 3 of 3

secondary exposure (e.g., multi-pet households).

- e. A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, I yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- g. A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- h. Table showing number of incidents for each dog breed.
- i. Table showing number of incidents in dogs for each clinical sign.
- j. Table showing number of incidents in dogs for each organ system.
- k. Report aggregate incidents, but do not combine moderate and minor incidents.
- 8. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.
- Virbac Inc. should adequately address all of the mitigation actions identified in the Agency's Generic Pet Spot-On Mitigation Plan available at the following internet site: http://www.epa.gov/pesticides/health/spot-on-meetings.html.

You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the Terms of Registration stated above, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact me Richard J. Gebken at (703) 305-6701 or gebken.richard@epa.gov.

Sincerely,

Richard Gebken Product Manager 10 Insecticide Branch

Registration Division (7505C)

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Enclosure

{Master Label} Virbac's Master Label

US-8 EPA Reg. No. 2382-XXX Version Date December 14, 2011 Fipronil + Pyriproxyfen Topical Solution for Dogs

Virbac EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING)(UP TO 22.9 LBS, [WEIGHING] 23 TO 44.9 LBS, [WEIGHING] 45 TO 88.9 LBS, [WEIGHING] 89 TO 132 lbs).

ACTIVE INGREDIENTS: Fipronil 9,7% OTHER INGREDIENTS: 87.4%

KEEP OUT OF REACH OF CHILDREN CAUTION

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

ACCEPTED with COMMENTS In EPA Letter Dated

July 6, 2012

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Possible temporary irritation may occur at the site where EFFIPRO® PLUS Topical Solution for Dogs was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides.

| | FIRST AID | | |
|----------------------------|--|--|--|
| tF SWALLOWED: | Call a poison control center or doctor immediately for treatment advice. | | |
| | Have person sip a glass of water if able to swallow. | | |
| | Do not induce vomiting unless told to do so by a poison control center or doctor. | | |
| | Do not give anything by mouth to an unconscious person. | | |
| tFIN EYES: | Hold eye open and rinse slowly and gently with water for 15-20 minutes. | | |
| | Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. | | |
| | Call a poison control center or doctor for treatment advice | | |
| IF ON SKIN OR CLOTHING: | Take off contaminated clothing. | | |
| | Rinse skin immediately with plenty of water for 15-20 minutes. | | |
| | Call a poison control center or doctor for treatment advice. | | |

Have product container or tabel with you when calting a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY, DO NOT USE ON CATS, KITTENS, OR RABBITS, OO NOT USE ON OTHER ANIMALS.

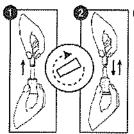
For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Starticks, and Deer ticks (that may [which may[transmit [carry] Lyme disease), mosquitoes and chewing lice; apply to OOGS or PUPPIES (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

- 1. Remove one applicator from packaging.
 - Hold applicator upright and remove cap.
- Inverticap and place other end back onto applicator tip. 2. Push cap down to break seal. Remove cap prior to treatment application.
- Part dog's hair between shoulder blades until skin is visible. 3.

Place applicator tip directly against exposed skin.

- За. For small dogs (12 weeks old or older) and weighing up to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- For medium dogs 23-44.9 lbs or targe dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's 3b. back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty. Ensure that EFFIPRO® PLUS Topical Solution for Dogs is not applied superficially on dog's











FREQUENCY OF APPLICATION

Research has shown that flea, tick and chewing fice infestations can be controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.

Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Dogs can control flea eggs for up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Oogs can kill ticks for a month or longer. Apply monthly where tick control is

consistently needed.

Chewing Lice: EFF!PRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Dogs. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIOEFCONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this

warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

How supplied: For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and pupples 8 weeks old or older and up to 22.9 lbs (0.023 fl oz)/(0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz)/(1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz)/(2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz)/(4.02 mL).

Net Contents:

1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.023 ft oz (0.67 mL), 0.045 ft oz (1.34 mL), 0.09t ft oz (2.68 mL), or 0.136 ft oz (4.02 mL) (of solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

EPA Reg. No. 2382-xxx EPA Est. No. 2382-xxxx

VIRBAC AH, INC. PO BOX 162059 FORT WORTH, TX 76161 1-800-338-3659

Made in France EFFIPRO® is a registered trademark of Virbac S.A. in the United States Questions or comments? Call: [-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application Open resealable label for directions for use Open resealable label for directions for use and storage and disposal See back panel for additional precautionary statements See package insert(s) for frequency of application See enclosed insert(s) for directions for use and storage and disposal See enclosed insert(s) for directions for use

Photograph of dog or puppy

Lift here to open (LIFT HERE TO OPEN) For Use on Dogs only Use only on dogs

{Text for Foil of Blister package}

Virbac
EFFIPRO® PLUS Topical Solution for Dogs
Only for use (on dogs up to 22.9 lbs, on dogs 23-44.9 lbs, on dogs 45-88.9 lbs, on dogs 89-132 lbs) / (0.023 ft oz [0.67 mL], 0.045 ft oz [1.34 mL], 0.09 f fl oz [2.68 mL], 0.136 ft oz [4.02 mL]).
Contains fipronil (9.7%) and pyriproxyfen (2.9%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label /or additional directions
EPA Reg. No. 2382-xxx

{Text for Applicator Tube}

Virbac
EFFIPRO® PLUS
Topical Solution for Dogs
Onty for use on dogs
up to 22.9 lbs (23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)
0.023 ft oz [0.67 mL] (0.045 ft oz [1.34 mL], 0.091 ft oz [2.68 mL], 0.136 ft oz [4.02 mL])
Contains fipronit (9.7%) and pyriproxyfen (2.9%)
KEEP OUT OF REACH
OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-xxx

MARKETING CLAIMS

[Multiple infestations]

- · For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice.
- For convenient, quick-acting, tong-tasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice.
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient fipronil, which controls infestations caused
 by fleas, ticks, mosquitoes and chewing lice (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to
 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient pyriproxyfen, which controls reinfestations
 caused by fleas eggs and flea larvae (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs,
 weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is avaitable in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz) (0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz) (1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz) (2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz) (4.02 mL).
- For killing fleas, (flea eggs, flea larvae.) all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that [which] may transmit]carry) Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks)
- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- . Kills fleas and ticks for up to one month (4 weeks)
- · Apply monthly for control and prevention of fleas and ticks
- Kills fleas and ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, bartonellosis (and hepatozoonosis).
- Kills fleas, (flea eggs, flea larvae.) ticks, mosquitoes and chewing lice
- Kills fleas, (flea eggs, flea tarvae,) ticks, mosquitoes and tice
- · Effective monthly control of fleas and ticks
- Effective monthly application for fleas and ticks
- · Effective monthly application for dogs against fleas and ticks
- · Single application kills fleas and ticks
- . Single application lasts 4 weeks (one month)
- Research has shown that flea, tick and chewing lice infestations can be completely controlled with monthly
 applications of EFFIPRO® PLUS Topical Solution for Dogs.

Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFÍPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

]Fleas]

- Kills newly emerged adult fleas prior to egg laying
- Kills fleas, flea eggs and flea larvaa
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupee and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pynproxyfen (IGR)* to break flea life cycle
- * insect growth regulator
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit (bartonellosis), (tularemia) (and) (tapeworm)
- Kills fleas that may transmit (bartonellosis), (lularemia) (and) (tapeworm infestations).
- Kills fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- · Effective monthly application against fleas
- · Effective monthly control of fleas
- Kills adult fleas for up to one month (4 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts 1 month (4 weeks)
- East to apply, flea control that lasts up to t (one) month (4 weeks)
- EFFIPRO PLUS Topical Solution for Dogs kills fleas on your dog
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
 Kills fleas which (that) may cause flea-bite anemia
- Fleas do not have to bite to die
- EFFtPRO® PLUS Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichlosis), and Lone Star ticks (that may transmit hepatozoonosis) for up to one month (4 weeks).
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (Rhipicephalus spp), American dog ticks (Dermacentor variabilis), Deer ticks (txodes spp) and Lone Star ticks (Amblyomma americanum) for up to one month (4 weeks).
- Kills (Lone Star ticks) (Amblyomma americanum) for 4 weeks (for up to one month).
- Effective monthly application against ticks

[Mosquitoes]

- Kills mosquitoes
- · Kills mosquitoes for up to 28 days

[Alt others]

- EFFIPRO® PLUS Topical Solution for Dogs aids in (the) control of sarcoptic mange mite infestations.
- · Aids in (the) control of sarcoptic mange mite infestations
- Elimination of sarcoptic mange mites may require multiple monthly applications.
- · Chewing lice infestations are rapidly eliminated
- · May be used on pupples from 8 weeks of age
- Only for dogs and puppies 8 weeks old or older (weighing up to 22.9 lbs, 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy, spot-on (topical) application
- Convenient topical application for dogs
- · Easy to apply spot-on (topical) application
- Ouick drying, non-greasy
- Convenient, easy to apply
- Easy and convenient application (applications)
- Convenient to use (easy to apply)
- · Once monthly application
- Single application lasts up to 4 weeks (1 month) (one month)
- t (3, 6 or 36) applicator(s) (tube(s)) 0.023 fl oz (0.67 mL)
- t (3, 6 or 36) applicator(s) [tube(s)] 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.09 t fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.136 fl oz (4.02 mL)
- t (3, 6, 36) month(ly) dose(s) (applications)
- t (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) (each) containing 0.091 fl oz (2.68 mL)
- t (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0 t36 fl oz (4.02 mL)
- 1 applicator (tube) t month(ly) dose
- 3 applicators (tubes) 3 monthly doses (applications)
- · 6 applicators (tubes) 6 monthly doses (applications)
- 36 applicators (tubes) 36 monthly doses (applications)
- 1 (3, 6, 36) applicator(s) containing 0.023 fl oz [0.67 mL], (0.045 fl oz (1.34 mL), 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL])
- · Available from veterinarians
- Remains effective after exposure to sunlight
- · Remains effective after bathing and swimming
- · Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- . Still works after bathing, swimming or exposure to sunlight
- Still works after exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- EFFIPRO® PLUS Topical Solution for Dogs is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof (remains effective after bathing and swimming)

{Master Label} Virbac's Master Label

Date December 14, 2011 Version US-8 EPA Reg. No. 2382-XXX

Fipronil + Pyriproxyfen Topical Solution for Dogs

Virbac EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING) (UP TO 22.9 LBS, [WEIGHING] 23 TO 44.9 LBS, [WEIGHING] 45 TO 88.9 LBS, [WEIGHING] 89 TO 132 lbs).

ACTIVE INGREDIENTS:

KEEP OUT OF REACH OF CHILDREN CAUTION

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye imitation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use onty. Do not use on pupples under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO® PLUS Topical Solution for Dogs was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs.

| | FIRST AID | |
|----------------------------|--|--|
| IF SWALLOWED: | Call a poison control center or doctor immediately for treatment advice. | |
| | Have person sip a glass of water if able to swallow. | |
| | Do not induce vomiting unless told to do so by a poison control center or doctor. | |
| | Do not give anything by mouth to an unconscious person. | |
| IF IN EYES: | Hold eye open and rinse slowly and gently with water for 15-20 minutes. | |
| | Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. | |
| | Call a poison control center or doctor for treatment advice. | |
| IF ON SKIN OR CLOTHING: | Take off contaminated clothing. | |
| | Rinse skin immediately with plenty of water for 15-20 minutes. | |
| | Call a poison control center or doctor for treatment advice. | |

You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.

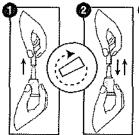
DIRECTIONS FOR USE

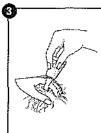
It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY, USE ON DOGS ONLY, DO NOT USE ON RABBITS, DO NOT USE ON OTHER ANIMALS.

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may (which may) transmit [carry] Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

- Remove one applicator from packaging. Hold applicator upright and remove cap.
- 2. Inverticap and place other end back onto applicator tip. Push cap down to break seal.
- Remove cap prior to treatment application.
- 3. Part dog's hair between shoulder blades until skin is visible. Place applicator tip directly against exposed skin.
- For small dogs (12 weeks old or older) and weighing up to 22.9 tbs-Deposit 3a. entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's Зb. back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b. squeezing the applicator until emply.
- 3¢. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty. Ensure that EFFIPRO® PLUS Topical Solution for Dogs is not applied superficially on dog's hair.











FREQUENCY OF APPLICATION

Research has shown that flea, tick and chewing lice infestations can be controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.

Fteas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas for up to three months. Apply monthly if your dog has fleas that may cause Flea Altergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Dogs can control flea eggs for up to three months (90 days).
Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is

consistently needed.

Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Dogs. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE/CONTAINER DISPOSAL: If empty: Nonrefillable container, Do not reuse or refill this container. Offer for recycling, if available. If partially fitted: Call your tocal solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

How supplied: For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and pupples 8 weeks old or older and up to 22.9 lbs (0.023 fl oz)/(0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz)/(1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz)/(2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz)/(4.02 mL).

Net Contents:

1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.023 fl oz (0.67 mL), 0.045 fl oz (1.34 mL), 0.091 fl oz (2.68 mL), or 0.136 fl oz (4.02 mL) (of solution).

(Detachable) catendar (monthly application) reminder stickers (with illustration of dog or puppy)

EPA Reg. No. 2382-xxx EPA Est. No. 2382-xxxx

VIRBAC AH, INC. PO BOX 162059 FORT WORTH, TX 76161 1-800-338-3659

Made in France EFFIPRO $^{\circ}$ is a registered trademark of Virbac S.A. in the United States Questions or comments? Calt: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application Open resealable label for directions for use Open resealable label for directions for use and storage and disposal See back panel for additional precautionary statements See package insert(s) for frequency of application See enclosed insert(s) for directions for use and storage and disposal See enclosed insert(s) for directions for use

Photograph of dog or puppy

Lift here to open (LIFT HERE TO OPEN) For Use on Dogs onty Use only on dogs

{Text for Foil of Blister package}

EFFIPRO® PLUS Topical Solution for Dogs
Onty for use (on dogs up to 22.9 lbs, on dogs 23-44.9 lbs, on dogs 45-88.9 lbs, on dogs 89-132 lbs) / (0.023 fl oz [0.67 mL], 0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL]).
Contains tipronit (9.7%) and pyriproxyfen (2.9%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-xxx

{Text for Applicator Tube}

Virbac
EFFIPRO® PLUS
Topical Solution for Dogs
Only for use on dogs
up to 22.9 tbs (23-44.9 tbs, 45-88.9 lbs, 89-132 lbs)
0.023 fl oz [0.67 mL] (0.045 fl oz [1.34 mL], 0.091 ft oz [2.68 mL], 0.136 fl oz [4.02 mL])
Contains fipronil (9.7%) and pyriproxyfen (2.9%)
KEEP OUT OF REACH
OF CHILDREN
CAUTION
See full tabel for additional directions
EPA Reg. No. 2382-xxx

MARKETING CLAIMS

(Multiple infestations)

- · For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice.
- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice.
- EFF!PRO® PLUS Topical Solution for Dogs contains the active ingredient fipronil, which controls infestations caused
 by fleas, ticks, mosquitoes and chewing lice (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to
 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient pyriproxyfen, which controls reinfestations
 caused by fleas eggs and flea larvae (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs,
 weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 ft oz) (0.67 mL), medium dogs 23-44.9 lbs (0.045 ft oz) (1.34 mL), large dogs 45-88.9 lbs (0.091 ft oz) (2.68 mL), and extra large dogs 89-t32 lbs (0.136 ft oz) (4.02 mL).
- For killing fleas, (tlea eggs, flea larvae.) all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that (which) may transmit (carry) Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks)
- · Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- . Kills fleas and ticks for up to one month (4 weeks)
- Apply monthly for control and prevention of fleas and ticks
- Kills fleas and ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, bartonellosis (and hepafozoonosis).
- Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and chewing lice
- · Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and lice
- Effective monthly control of fleas and ticks
- Effective monthly application for fleas and ticks
- · Effective monthly application for dogs against fleas and ticks
- Single application kills fleas and ticks
- Single application lasts 4 weeks (one month)
- Research has shown that flea, tick and chewing lice infestations can be completely controlled with monthly
 applications of EFFIPRO® PLUS Topical Solution for Doos.

applications of EFFIPRO® PLUS Topical Solution for Dogs.

Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas, flea eggs and flea (arvae for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely.

Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

(Fleas)

- . Kills newly emerged adult fleas prior to egg laying
- · Kills fleas, flea eggs and flea farvae
- · Sterilizes and kills (adult) fleas
- · Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR) to break flea life cycle
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kills fleas that may transmit bartonellosis
- · Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia (and tapeworm infestations).
- . Kills fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly application against fleas
- · Effective monthly control of fleas
- . Kills adult fleas for up to one month (4 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts it month (4 weeks)
- East to apply, flea control that lasts up to t (one) month (4 weeks)
- EFFIPRO® PLUS Topical Solution for Dogs kills fleas on your dog
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- Kills fleas which (that) may cause flea-bite anemia
- Fleas do not have to bite to die
- EFFIPRO® PLUS Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatifis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitls (FAD)
- Prevents tlea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those that may Iransmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, enrichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatozoonosis) for up to one month (4 weeks).
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (Rhipicephalus spp), American dog ticks (Dermacentor variabilis), Deer ticks (Ixodes spp) and Lone Star ticks (Amblyomma americanum) for up to one month (4 weeks).
- Kills Ambiyomma americanum (Lone Star ticks) for 4 weeks (for up to one month).
- Effective monthly application against ticks

[Mosquitoes[

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

[Atl others]

- EFFIPRO® PLUS Topical Solution for Dogs aids in (the) control of sarcoptic mange mite infestations,
- Aids in (the) control of sarcoptic mange mite infestations
- Elimination of mites may require multiple monthly applications.
- Chewing lice infestations are rapidly eliminated
- May be used on puppies from 8 weeks of age
- Only for dogs and pupples 8 weeks old or older (weighing up to 22.9 lbs, 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy, spot-on (topical) application
- Convenient topical application for dogs
- Easy to apply spot-on (topicat) application
- Quick drying, non-greasy
- Convenient, easy to apply
- Easy and convenient application (applications)
- Convenient to use (easy to apply)
- Once monthly application
- Single application lasts up to 4 weeks (1 month) (one month)
- t (3, 6 or 36) applicator(s) [tube(s)[0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)) 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.091 fl oz (2.68 mL) 1 (3, 6 or 36) applicator(s) [tube(s)] 0.136 fl oz (4.02 mL)
- 1 (3, 6, 36) month(ly) dose(s) (applications)
- 1 (3, 6 or 36) applicator(s) (tube(s)[(each) containing 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)[(each) containing 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)[(each) containing 0.091 ft oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)[(each) containing 0.136 fl oz (4.02 mL)
- t applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 monthly doses (applications)
- 6 applicators (tubes) 6 monthly doses (applications)
- 36 applicators (tubes) 36 monthly doses (applications)
- t (3, 6, 36) applicator(s) containing 0.023 fl oz (0.67 mL[, (0.045 fl oz [t.34 mL[, 0.091 fl oz [2.68 mL[, 0.136 fl oz [4.02
- Available from licensed veterinarians
- Remains effective after exposure to sunlight
- Remains effective after bathing and swimming
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, swimming or exposure to sunlight
- Still works after exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- EFFIPRO® PLUS Topical Solution for Dogs is effective after bathing, shampooing, water immersion, or sunlight
- Waterproof (remains effective after bathing and swimming)

{Master Label} Virbac's Master Label

Date December 14, 2011 Version US-8 EPA Reg. No. 2382-XXX Fipronil + Pyriproxyfen Topical Solution for Dogs

Virbac EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING) (UP TO 22.9 LBS, [WEIGHING] 23 TO 44.9 LBS, [WEIGHING] 45 TO 88.9 LBS, [WEIGHING] 89 TO 132 lbs).

| ACTIVE INGREDIENTS 49 | |
|-----------------------|------|
| Fipronil | 9.7% |
| Pyriproxyfen | 2.9% |
| OTHER INGREDIENTS: | |
| · ~~~ | |

KEEP OUT OF REACH OF CHILDREN CALLION READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO® PLUS Topical Solution for Dogs was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs.

| | FIRST AID |
|---------------|--|
| IF SWALLOWED: | Call a poison control center or doctor immediately for treatment advice. |
| | Have person sip a glass of water if able to swallow. |
| | Do not induce vomiting unless told to do so by a poison control center or doctor. |
| | Do not give anything by mouth to an unconscious person. |
| tF IN EYES: | Hold eye open and rinse slowly and gently with water for 15-20 minutes. |
| | Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. |
| | Call a poison control center or doctor for treatment advice. |
| IF ON SKIN OR | Take off contaminated clothing. |
| CLOTHING: | Rinse skin immediately with plenty of water for 15-20 minutes. |
| | Call a poison control center or doctor for treatment advice. |

You may also contact the Hottine number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.

DIRECTIONS FOR USE

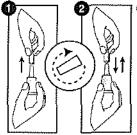
tt is a violation of Federal taw to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer tlcks (that may [which may] transmit (carry] Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

- Remove one applicator from packaging. Hold applicator upright and remove cap.
- Invert cap and place other end back onto applicator tip.

 Push cap down to break seal.
 - Remove cap prior to treatment application.
- 3. Part dog's hair between shoulder blades until skin is visible.
- Place applicator tip directly against exposed skin.
- 3a. For small dogs (12 weeks old or otder) and weighing up to 22.9 tbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spols on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra targe dogs 89-132 ths- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty. Ensure that EFFIPRO® PLUS Topical Solution for Dogs is not applied superficially on dog's hair.











FREQUENCY OF APPLICATION

Research has shown that flea, tick and chewing lice infestations can be controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.

Fleas: EFFIPRO® PLUS Topicat Solution for Dogs can kill adult fleas for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Dogs can control flea eggs for up to three months (90 days).

control flea eggs for up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kilt chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours for up to 7 days and within 48 hours for up to 28 days.

Notés: Wait at teast 30 days before re-application of EFFIPRO® PLUS Topicat Solution for Dogs. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container onty, out of reach of children and animats.

PESTICIDE/CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, if partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to labet instructions. To the extent consistent with applicable taw, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

How supplied: For easy and convenient application, EFFIPRO® PLUS Topical Solution for Oogs is available in sizes for small dogs and pupples 8 weeks old or older and up to 22.9 lbs (0.023 fl oz)/(0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz)/(1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz)/(2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz)/(4.02 mL).

Net Contents:

1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.023 ft oz (0.67 mL), 0.045 ft oz (1.34 mL), 0.091 ft oz (2.68 mL), or 0.136 ft oz (4.02 mL) (of solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

EPA Reg. No. 2382-xxx EPA Est. No. 2382-xxxx

VIRBAC AH, INC. PO BOX 162059 FORT WORTH, TX 76161 1-800-338-3659

Made in France EFFIPRO® is a registered trademark of Virbac S.A. in the United States Questions or comments? Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application Open resealable label for directions for use Open resealable label for directions for use and storage and disposal See back panel for additional precautionary statements See package insert(s) for frequency of application See enclosed insert(s) for directions for use and storage and disposal See enclosed insert(s) for directions for use

Photograph of dog or puppy

Lift here to open (LIFT HERE TO OPEN) For Use on Dogs only Use only on dogs

{Text for Foil of Blister package}

EFFIPRO® PLUS Topical Solution for Dogs
Onty for use (on dogs up to 22.9 lbs, on dogs 23-44.9 lbs, on dogs 45-88.9 lbs, on dogs 89-132 lbs) / (0.023 fl oz [0.67 mL], 0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL]).
Contains fipronil (9.7%) and pyriproxyfen (2.9%)
KEEP OUT OF REACH OF CHILOREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-xxx

{Text for Applicator Tube}

Virbac
EFFIPRO® PLUS
Topical Solution for Dogs
Only for use on dogs
up to 22.9 tbs (23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)
0.023 fl oz [0.67 mL] (0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL])
Contains fipronil (9.7%) and pyriproxyfen (2.9%)
KEEP OUT OF REACH
OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-xxx

MARKETING CLAIMS

[Multiple infestations)

- / . For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice.
- /• For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice.
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient pyriproxyfen, which controls reinfestations
 caused by fleas eggs and flea larvae (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs,
 weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz) (0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz) (1.34 mL), large dogs 45-88.9 lbs (0.09 t fl oz) (2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz) (4.02 mL).
- For killing fleas, (flea eggs, flea larvae,) all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that [which) may transmit [carry) Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks)
- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- Kills tleas and ticks for up to one month (4 weeks)
- Apply monthly for control and prevention of fleas and ticks
- Kills fleas and ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, bartonellosis (and hepalozoonosis).
- · Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and chewing lice
- Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and lice
- Effective monthly control of fleas and ticks
- Effective monthly application for fleas and ticks
- · Effective monthly application for dogs against fleas and ticks
- Single application kills fleas and ticks
- Single application lasts 4 weeks (one month)
- Research has shown that flea, tick and chewing lice infestations can be completely controlled with monthly
 applications of EFFIPRO® PLUS Topical Solution for Dogs.
 Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas, flea eggs and flea larvae for up to three

Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours for up to 7 days and within 48 hours for up to 28 days.

(Fleas)

- Kills newly emerged adult fleas prior to egg laying
- Kills fleas, flea eggs and flea larvae
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- ... With pyriproxyfen (IGR) to break flea life cycle
- -- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia (and tapeworm infestations).
- Kills fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly application against fleas
- Effective monthly control of fleas
- Kills adult fleas for up to one month (4 weeks)
- ... Kills fleas
- Easy to apply, control of (for) fleas that lasts 1 month (4 weeks)
- East to apply, flea control that lasts up to 1 (one) month (4 weeks)
- ◆ EFFIPRO® PLUS Topical Solution for Dogs kills fleas on your dog
- Kills adult fleas which may cause Flea Allergy Dermalitis (FAD)
- Kills fleas which (that) may cause flea-bite anemia
- Fleas do not have lo bite to die
- EFFIPRO® PLUS Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatozoonosis) for up to one month (4 weeks).
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (Rhipicephalus spp), American dog ticks (Dermacentor variabilis), Deer ticks (fxodes spp) and Lone Star ticks (Amblyomma americanum) for up to one month (4 weeks).
- Kills Ambfyomma americanum (Lone Star ticks) for 4 weeks (for up to one month).
- Effective monthly application against ticks

[Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

[Att others[

- EFFtPRO® PLUS Topical Solution for Dogs aids in (the) control of sarcoptic mange mite infestations.
- Aids in (the) control of sarcoptic mange mite infestations
- Elimination of mites may require multiple monthly applications.
- Chewing lice infestations are rapidly eliminated
- May be used on pupples from 8 weeks of age
- Only for dogs and puppies 8 weeks old or older (weighing up to 22.9 lbs, 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy, spot-on (topical) application
- Convenient topical application for dogs
- · Easy to apply spot-on (topical) application
- Quick drying, non-greasy
- Convenient, easy to apply
- · Easy and convenient application (applications)
- Convenient to use (easy to apply)
- Once monthly application
- Single application lasts up to 4 weeks (1 month) (one month)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.023 froz (0.67 ftt)
 1 (3, 6 or 36) applicator(s) [tube(s)] 0.045 floz (1.34 mL)
- t (3, 6 or 36) applicator(s) (tube(s)] 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.136 fl oz (4.02 mL)
- 1 (3, 6, 36) month(ty) dose(s) (applications)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.023 tl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.045 fl oz (1.34 mL)
- t (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.091 fl oz (2.68 mL)
- t (3, 6 or 36) applicator(s) [tube(s)) (each) containing 0.136 fl oz (4.02 mL)
- t applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 monthly doses (applications)
- 6 applicators (tubes) 6 monthly doses (applications)
- 36 applicators (tubes) 36 monthly doses (applications)
- 1 (3, 6, 36) applicator(s) containing 0.023 fl oz (0.67 mL], (0.045 tl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mLf)
- Available from licensed veterinarians
- · Remains effective after exposure to sunlight
- · Remains effective after bathing and swimming
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- · Remains effective even after bathing
- · Remains effective after exposure to rain and sunlight
- · Still works after bathing, swimming or exposure to sunlight
- Still works after exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- EFFIPRO® PLUS Topical Solution for Dogs is effective after bathing, shampooing, water immersion, or sunlight
 exposure.
- · Waterproof (remains effective after bathing and swimming)



{Master Label} Virbac's Master Label

US-8 Version EPA Reg. No. 2382-XXX Date December 14, 2011 Fipronil + Pyriproxyfen Topical Solution for Dogs



Trbacoved Label Copy Topical Solution For

DOGS

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING) (UP TO 22.9 LBS, [WEIGHING] 23 TO 44.9 LBS, [WEIGHING] 45 TO 88.9 LBS, [WEIGHING] 89 TO 132 Ibs);

ACTIVÉ INGREDIENTS:

KEEP OUT OF REACH OF CHILDREN CAUTION

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gurn, using tobacco, or using the toitet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO® PLUS Topical Solution for Dogs was applied. Contact a veterinarian immediatety if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial apptication, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs.

| | FIRST AID | | |
|----------------------------|--|--|--|
| IF SWALLOWED: | Call a poison control center or doctor immediately for treatment advice. | | |
| | Have person sip a glass of water if able to swallow. | | |
| | Do not induce vomiting unless told to do so by a poison control center or doctor. | | |
| | Do not give anything by mouth to an unconscious person. | | |
| IF IN EYES: | Hold eye open and rinse slowly and gently with water for 15-20 minutes. | | |
| | Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. | | |
| | Call a poison control center or doctor for treatment advice. | | |
| IF ON SKIN OR CLOTHING: | Take off contaminated clothing. | | |
| | Rinse skin immediately with plenty of water for 15-20 minutes. | | |
| | Call a poison control center or doctor for treatment advice. | | |

Have product container or tabet with you when catting a polson control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency

medical treatment information or pesticide incidents.

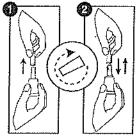
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY, DO NOT USE ON RABBITS, DO NOT USE ON OTHER ANIMALS,

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may [which may] transmit [carry] Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

- Remove one applicator from packaging. Hold applicator upright and remove cap.
- 2. Inverticap and place other end back onto applicator tip. Push cap down to break seal. Remove cap prior to treatment application.
- Part dog's hair between shoulder blades until skin is visible. 3.
- Place applicator tip directly against exposed skin.
 For small dogs (12 weeks old or older) and weighing up to 22.9 lbs- Deposit За. entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's 3b. back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the 3c. shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty. Ensure that EFFIPRO® PLUS Topical Solution for Dogs is not applied superficially on dog's











FREQUENCY OF APPLICATION

Research has shown that flea, tick and chewing lice infestations can be controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.

Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Dogs can control flea eggs for up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewlng Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Dogs. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE/CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially fitted: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

How supptied: For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 ft oz)/(0.67 mL), medium dogs 23-44.9 lbs (0.045 ft oz)/(1.34 mL), large dogs 45-88.9 lbs (0.091 ft oz)/(2.68 mL), and extra large dogs 89-132 lbs (0.136 ft oz)/(4.02 mL).

Net Contents:

t, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains $0.023~\mathrm{fl}$ oz $(0.67~\mathrm{mL})$, $0.045~\mathrm{fl}$ oz $(1.34~\mathrm{mL})$, $0.09t~\mathrm{tl}$ oz $(2.68~\mathrm{mL})$, or $0.136~\mathrm{tl}$ oz $(4.02~\mathrm{mL})$ (ot solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

EPA Reg. No. 2382-xxx EPA Est. No. 2382-xxxx

VIRBAC AH, INC. PO BOX 162059 FORT WORTH, TX 76161 1-800-338-3659

Made in France EFFIPRO® is a registered trademark of Virbac S.A. in the United States Questions or comments? Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application Open reseafable label for directions for use Open reseafable label for directions for use and storage and disposal See back panel for additional precautionary statements See package insert(s) for frequency of application See enclosed insert(s) for directions for use and storage and disposal See enclosed insert(s) for directions for use

Photograph of dog or puppy

Lift here to open (LIFT HERE TO OPEN) For Use on Dogs only Use only on dogs

{Text for Foil of Blister package}

EFFIPRO® PLUS Topical Solution for Dogs

Only for use (on dogs up to 22.9 lbs, on dogs 23-44.9 lbs, on dogs 45-88.9 lbs, on dogs 89-132 lbs) / (0.023 ft oz [0.67 mL], 0.045 ft oz [1.34 mL], 0.091 ft oz [2.68 mL], 0.136 tt oz [4.02 mL]).

Contains fipronit (9.7%) and pyriproxyfen (2.9%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See tull tabel for additional directions

EPA Reg. No. 2382-xxx

{Text for Applicator Tube}

Virbac
EFFIPRO® PLUS
Topical Solution for Dogs
Only for use on dogs
up 10 22.9 lbs (23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)
0.023 fl oz [0.67 mL] (0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL])
Contains fipronil (9.7%) and pyńproxyfen (2.9%)
KEEP OUT OF REACH
OF CHILDREN
CAUTION
See tull label for additional directions
EPA Reg. No. 2382-xxx

MARKETING CLAIMS

[Multiple infestations]

- · For convenient, quick-acting, long-tasting, effective control of fleas, ticks, mosquitoes and chewing lice.
- For convenient, quick-acting, tong-tasting, effective control of tleas, tlea eggs, tlea larvae, ticks, mosquitoes and chewing lice.
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient fipronil, which controls intestations caused
 by fleas, ticks, mosquitoes and chewing lice (on dogs) (DOGS or PUPPLES) (8 weeks old or older) (weighing up to
 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient pyriproxyfen, which controls reintestations
 caused by tleas eggs and tlea larvae (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs,
 weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 ibs (0.023 tl oz) (0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz) (1.34 mL), targe dogs 45-88.9 lbs (0.09 t tl oz) (2.68 mL], and extra large dogs 89-132 lbs (0.136 tl oz) (4.02 mL).
- For killing fleas, (flea eggs, flea larvae.) all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that [which] may transmit [carry] Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPLES (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy tor up to one month (4 weeks)
- · Prevents flea and tick (re-)intestation for up to one month (4 weeks)
- . Kills fleas and ticks tor up to one month (4 weeks)
- Apply monthly tor control and prevention of treas and ticks
- Kills tleas and ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, bartonellosis (and hepatozoonosis).
- Kills tleas, (flea eggs, flea larvae.) ticks, mosquitoes and chewing lice
- Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and lice
- · Effective monthly control of fleas and ticks
- · Effective monthly application for tleas and ticks
- · Effective monthly application for dogs against fleas and ticks
- Single application kills fleas and ticks
- Single application lasts 4 weeks (one month)
- Research has shown that tlea, tick and chewing lice intestations can be completely controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.

 Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult tleas, flea eggs and flea larvae for up to three

Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult tleas, flea eggs and flea larvae for up to three months. Apply monthly it your dog has fleas that may cause Flea Allergy Dermatilis (FAD), or it reintestation is likely. Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

[Fteas]

- · Kills newly emerged adult fleas prior to egg laying
- Kills fleas, tlea eggs and flea tarvae
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and tlea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR) to break tlea lite cycle
- Dual Action(!): fipronil and pyriproxyfen (!GR) effectively breaks the tlea lite cycle
- Kills fleas that may transmit bartonellosis
- · Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills tleas that may transmit diseases, including bartonellosis, tularemia (and tapeworm infestations).
- · Kilts tleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Ettective monthly application against tleas
- Effective monthly control of tleas
- Kills adult fleas for up to one month (4 weeks)
- Kills tleas
- Easy to apply, control ot (for) fleas that lasts 1 month (4 weeks)
- East to apply, tlea control that lasts up to 1 (one) month (4 weeks)
- EFFIPRO® PLUS Topical Solution for Dogs kills tleas on your dog
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)

 Kills flees which (that) may says flee hits graphic.
- Kills fleas which (that) may cause flea-bite anemia
- Fleas do not have to bite to die
- EFFIPRO® PLUS Topicat Solution for Dogs rapidty kilts fleas that may cause FAD (Flea Allergy Dermatitis)
- The successive teeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaptasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatozoonosis) for up to one month (4 weeks).
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (Rhipicephalus spp), American dog ticks (Dermacentor variabilis), Deer ticks (Ixodes spp) and Lone Star ticks (Amblyomma americanum) for up to one month (4 weeks).
- Kills Amblyomma americanum (Lone Starticks) for 4 weeks (for up to one month).
- Effective monthly application against ticks

(Mosquitoes)

- · Kills mosquitoes
- Kills mosquitoes for up to 28 days

(All others]

- EFFIPRO[®] PLUS Topical Solution for Dogs aids in (the) control of sarcoptic mange mite infestations.
- Aids in (the) control of sarcoptic mange mite infestations
- Elimination of mites may require multiple monthly applications.
- · Chewing lice infestations are rapidly eliminated
- · May be used on puppies from 8 weeks of age
- Only for dogs and puppies 8 weeks old or older (weighing up to 22.9 lbs, 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy, spot-on (topical) application
- · Convenient topical application for dogs
- Easy to apply spot-on (topical) application
- · Quick drying, non-greasy
- · Convenient, easy to apply
- · Easy and convenient application (applications)
- Convenient to use (easy to apply)
- · Once monthly application
- Single application lasts up to 4 weeks (1 month) (one month)
- 1 (3, 6 or 36) applicator(s) (tube(s)] 0.023 ft oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)) 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)] 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)] 0.136 fl oz (4.02 mL)
- t (3, 6, 36) month(ly) dose(s) (applications)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.045 ft oz (1.34 mL)
- t (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.09t tl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) (tube(s)] (each) containing 0.136 fl oz (4.02 mL)
- 1 applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 monthly doses (applications)
- 6 applicators (tubes) 6 monthly doses (applications)
- 36 applicators (tubes) 36 monthly doses (applications)
- 1 (3, 6, 36) applicator(s) containing 0.023 fl oz (0.67 mL], (0.045 fl oz (1.34 mL], 0.091 fl oz (2.68 mL), 0.136 fl oz (4.02 mL))
- Available from licensed veterinarians
- · Remains effective after exposure to sunlight
- · Remains effective after bathing and swimming
- · Remains effective even after bathing, water immersion or exposure to rain or sunlight
- · Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, swimming or exposure to sunlight
- · Still works after exposure to sunlight
- · Maintains residuat efficacy after bathing and swimming
- EFFIPRO® PLUS Topical Solution for Dogs is effective after bathing, shampooing, water immersion, or sunlight
 exposure.
- · Waterproof (remains effective after bathing and swimming)

(Master Label) Virbac's Master Label

Date December 14, 2011 Version US-8 EPA Reg. No. 2382-XXX Fipronil + Pyriproxyfen Topical Solution for Dogs

Virbac EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING) (UP TO 22.9 LBS, [WEIGHING] 23 TO 44.9 LBS, [WEIGHING] 45 TO 88.9 LBS, [WEIGHING] 89 TO 132 lbs).

| ACTIVE INGREDIENTS: | | 9.7% |
|---------------------|--------------------------------------|--------|
| | 94 (10) | 2.9% |
| | | |
| TOTAL: | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | t00.0% |

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye imitation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DDMESTIC ANIMALS

For external use only. Do not use on pupples under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO® PLUS Topical Solution for Dogs was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repealing application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs.

| | FIRST AID |
|----------------------------|--|
| IF SWALLOWED: | Call a poison control center or doctor immediately for treatment advice. |
| | Have person sip a glass of water if able to swallow. |
| | Do not induce vomiting unless told to do so by a poison control center or doctor. |
| | Do not give anything by mouth to an unconscious person. |
| IF IN EYES: | Hold eye open and rinse slowly and gently with water for 15-20 minutes. |
| | Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. |
| | Call a poison control center or doctor for treatment advice. |
| IF ON SKIN OR CLOTHING: | Take off contaminated clothing. |
| | Rinse skin immediately with plenty of water for 15-20 minutes. |
| | Call a poison control center or doctor for treatment advice. |

You may also contact the Hottine number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.

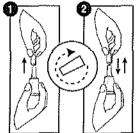
DIRECTIONS FOR USE

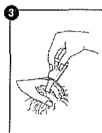
It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product, TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY, DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing tleas, flea eggs, tlea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may [which may] transmit [carry] Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as tollows:

APPLICATION DIRECTIONS

- Remove one applicator from packaging. Hold applicator upright and remove cap.
- Invert cap and place other end back onto applicator tip. Push cap down to break seal.
 - Remove cap prior to Ireatment application.
- 3. Part dog's hair between shoulder blades until skin is visible.
 - Place applicator tip directly against exposed skin.
- 3a. For small dogs (†2 weeks old or older) and weighing up to 22.9 lbs- Deposit entire contents by squeezing the entire applicator conlents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs. Apply the product eventy to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to tour spols on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spols as shown in diagram 3c, squeezing the applicator until empty. Ensure that EFFIPRO® PLUS Topical Solution for Dogs is not applied superficially on dog's hair.











FREQUENCY OF APPLICATION

Research has shown that flea, tick and chewing lice intestations can be controlled with monthly applications of EFFIPRO® PLUS Topical Solution for Dogs.

Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas for up to three months. Apply monthly it your dog has fleas that may cause Flea Allergy Dermatilis (FAD), or it reintestation is likely. EFFIPRO® PLUS Topical Solution for Dogs can control flea eggs for up to three months (90 days)

control flea eggs tor up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where fick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours (for up to 7 days) and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Dogs. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, tood, or teed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE/CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, it available. If partially tilled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or ouldoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

How supplied: For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and puppies 8 weeks old or older and up to 22.9 lbs (0.023 fl oz)/(0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz)/(1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz)/(2.68 mL), and extra large dogs 89-132 lbs (0.136 fl oz)/(4.02 mL).

Net Conten(s:

t, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.023 ff oz (0.67 mL), 0.045 fl oz (f.34 mL), 0.09 ff oz (2.68 mL), or 0, f36 fl oz (4.02 mL) (of solution).

(Defachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

EPA Reg. No. 2382-xxx EPA Esí. No. 2382-xxxx

VIRBAC AH, INC. PO BOX 162659 FORT WDRTH, TX 76161 1-800-338-3659

Made in France EFFIPRO® is a registered trademark of Virbac S.A. in the United States Questions or comments? Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application Open resealable label for directions for use Open resealable label for directions for use and storage and disposal See back panel for additional precautionary statements See package insert(s) for frequency of application See enclosed insert(s) for directions for use and storage and disposal See enclosed insert(s) for directions for use

Photograph of dog or puppy

Lift here to open (LIFT HERE TO OPEN) For Use on Dogs only Use only on dogs

{Text for Foil of Blister package}

Virbac

EFFIPRO® PLUS Topical Solution for Dogs
Only for use (on dogs up to 22.9 lbs, on dogs 23-44.9 lbs, on dogs 45-88.9 lbs, on dogs 89-132 lbs) / (0.023 fl oz [0.67 mL], 0.045 fl oz [1.34 mL], 0.091 fl oz [2.68 mL], 0.136 fl oz [4.02 mL]).
Contains fipronil (9.7%) and pyriproxyfen (2.9%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-xxx

{Text for Applicator Tube}

Virbac
EFFIPRO® PLUS
Topical Solution for Dogs
Only for use on dogs
up to 22.9 lbs (23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)
0.023 fl oz [0.67 mL] (0.045 fl oz [1.34 mL], 0.09 t fl oz [2.68 mL], 0.136 fl oz [4.02 mL])
Contains fipronil (9.7%) and pyriproxyfen (2.9%)
KEEP OUT OF REACH
OF CHILDREN
CAUTION
See full labet for additional directions
EPA Reg. No. 2382-xxx

MARKETING CLAIMS

[Multiple infestations)

- For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing fice.
- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient fipronit, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on dogs) (DOGS or PUPPIES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredient pyriproxyten, which controls reinfestations caused by fleas eggs and flea larvae (on dogs) (DOGS or PUPP!ES) (8 weeks old or older) (weighing up to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs).
- For easy and convenient application, EFFIPRO® PLUS Topical Solution for Dogs is available in sizes for small dogs and pupples 8 weeks old or older and up to 22.9 lbs (0.023 ft oz) (0.67 mL), medium dogs 23-44.9 lbs (0.045 fl oz) (1.34 mL), large dogs 45-88.9 lbs (0.091 fl oz) (2.68 mL), and extra large dogs 89-t32 lbs (0.136 fl oz) (4.02 mL).
- For killing fleas, (flea eggs, flea larvae,) all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that [which] may transmit [carry) Lyme disease), mosquitoes and chewing lice; apply to DOGS or PUPPIES (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks)
- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- Kills fleas and ticks for up to one month (4 weeks)
- Apply monthly for control and prevention of fleas and ticks
- Kills fleas and ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, bartonellosis (and hepatozoonosis).
- Kills fleas, (flea eggs, flea larvae,) ticks, mosquitoes and chewing lice
- Kills tleas, (flea eggs, flea larvae,) ticks, mosquitoes and lice
- Effective monthly control of fleas and ticks
- Effective monthly application for fleas and ticks
- Effective monthly application for dogs against tleas and ticks
- Single application kills fleas and ticks
- Single application lasts 4 weeks (one month)
- Research has shown that flea, tick and chewing lice infestations can be completely controlled with monthly

applications of EFFIPRO® PLUS Topical Solution for Dogs.
Fleas: EFFIPRO® PLUS Topical Solution for Dogs can kill adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause Flea Allergy Dermalitis (FAD), or if reinfestation is likely. Ticks: EFFIPRO® PLUS Topical Solution for Dogs can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewling Lice; EFFIPRO® PLUS Topical Solution for Dogs can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Dogs can kill mosquitoes within 24 hours

(for up to 7 days) and within 48 hours (for up to 28 days).

(Fleas)

- Kills newly emerged adult fleas prior to egg laying
- Kills fleas, flea eggs and flea larvae
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, tlea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR) to break flea life cycle
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia (and tapeworm infestations).
- Kills tleas that may cause Flea Allergy Dermalitis (FAD) or flea-bite anemia
- Effective monthly application against fleas
- Effective monthly control of fleas
- Kills adult fleas for up to one month (4 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts 1 month (4 weeks)
- East to apply, flee control that lasts up to 1 (one) month (4 weeks) EFFIPRO® PLUS Topical Solution for Dogs kills flees on your dog
- Kills adult fleas which may cause Flea Allergy Dermalitis (FAD)
- Kills fleas which (that) may cause flea-bite anemia
- Fleas do not have to bile to die
- EFFIPRO® PLUS Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Altergy Dermatitis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Altergy Dermatitis (FAD)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatozoonosis) for up to one month (4 weeks).
- Kitls ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (Rhipicephalus spp), American dog ticks (Dermacentor variabilis), Deer ticks (Ixodes spp) and Lone Star ticks (Amblyomma americanum) for up to one month (4 weeks).
- . Kills Amblyomma americanum (Lone Starticks) for 4 weeks (for up to one month).
- Effective monthly application against ticks

[Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

[All others]

- EFFIPRO® PLUS Topical Solution for Dogs aids in (the) control of sarcoptic mange mite infestations.
- · Aids in (the) control of sarcoptic mange mite infestations
- Elimination of mites may require multiple monthly applications.
- · Chewing tice infestations are rapidly eliminated
- May be used on pupples from 8 weeks of age
- Only for dogs and pupples 8 weeks old or older (weighing up to 22.9 lbs, 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- · Easy, spot-on (topical) application
- Convenient topical application for dogs
- · Easy to apply spot-on (topical) application
- Quick drying, non-greasy
- · Convenient, easy to apply
- · Easy and convenient application (applications)
- · Convenient to use (easy to appty)
- · Once monthly application
- Single application lasts up to 4 weeks (1 month) (one month)
- t (3, 6 or 36) applicator(s) [tube(s)] 0.023 fl oz (0.67 mL)
- t (3, 6 or 36) applicator(s) [tube(s)] 0.045 ft oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] 0.091 fl oz (2.68 mL)
- t (3, 6 or 36) applicator(s) (tube(s)) 0.136 fl oz (4.02 mL)
- t (3, 6, 36) month(ty) dose(s) (applications)
- 1 (3, 6 or 36) applicator(s) [tube(s)) (each) containing 0.023 fl oz (0.67 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)) (each) containing 0.045 fl oz (1.34 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.091 fl oz (2.68 mL)
 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.091 fl oz (2.68 mL)
- 1 (3, 6 or 36) applicator(s) [tube(s)] (each) containing 0.136 ft oz (4.02 mL)
- t applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 monthly doses (applications)
- 6 applicators (tubes) 6 monthly doses (applications)
- 36 applicators (tubes) 36 monthly doses (applications)
- t (3, 6, 36) applicator(s) containing 0.023 fl oz [0.67 mL], (0.045 fl oz [1.34 mL], 0.09 t fl oz [2.68 mL], 0. t36 fl oz [4.02 mL])
- Available from licensed veterinarians
- · Remains effective after exposure to sunlight
- Remains effective after bathing and swimming
- · Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- · Remains effective after exposure to rain and sunlight
- Still works after bathing, swimming or exposure to sunlight
- Still works after exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- EFFIPRO® PLUS Topical Solution for Dogs is effective after bathing, shampooing, water immersion, or sunlight
 exposure.
- Waterproof (remains effective after bathing and swimming)



VIRBAC rebuttal to the TRB review for 2382-RII dated 5-18-12

Byron Backus to: Richard Gebken Cc: John Redden, Masih Hashim

06/20/2012 04:10 PM

History:

This message has been forwarded.

After reviewing Virbac's rebuttal dated June 11, 2012, I have concluded that the MRIDs previously cited in support of EPA File Symbol 2382-RII will allow a claim for use on 8-week-old kittens. In addition, it is noted that 2382-RII is similar to 2382-186, except that 2382-RII includes 11.5% Pyriproxyfen, which has very low toxicity to mammalian species.

Efficacy Review

Date:

June 19, 2012

Efficacy Reviewer: Clayton Myers, Ph.D., Entomologist, RD-IB

mvers.clayton@epa.gov

703-347-8874

Risk Manager Rev.: Bonaventure Akinlosotu

Products:

EFFIPRO Plus Topical Solution for Dogs

EPA Reg. #:

2382-RIO

A.I.'s:

Fipronil (9.7%), Pyriproxyfen (2.9%)

Decision #s:

459013

DP #s:

398342

Submission:

R310, New Products, RD Science Review

MRIDs:

Submitted:

48696915, 48695015, 48695016, 48695017

Cited: 43121114, 43121115, 43121116, 43121117, 43121118, 43121119,

43121120, 43121121, 43121122, 43444901, 43577701, 43577712, 43577713, 43951701, 44088901, 46006002, 44900904, 45020601, 44942011, 44942106, 45612701, 45618501, 45620501, 45620502, 45620503, 45620504, 45620505, 45620506, 45628101, 45628102, 45628103, 45628104, 45628105, 45628201, 45866901, 45866902,

46019201, 46019202,

GLP:

Not all

Summary/Discussion of Submitted and Cited Efficacy Data:

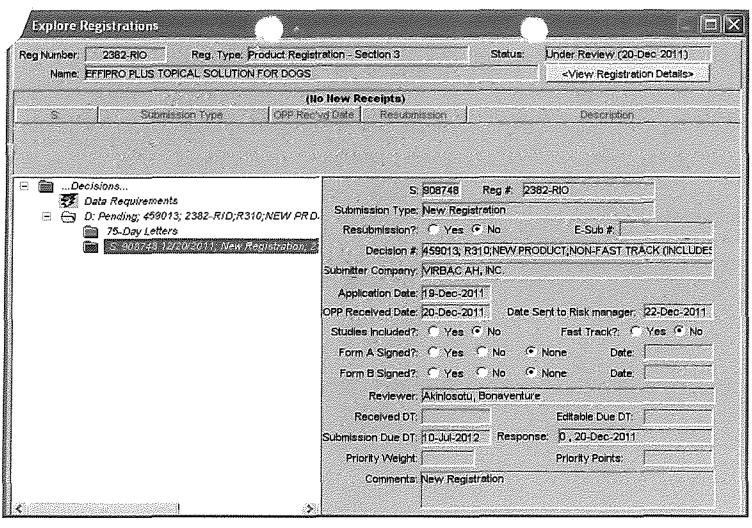
Efficacy claims are supported for control the following pests on dogs for one month:

- 1. Fleas (adults, eggs, and larvae). A six week duration claim is supported for flea adults, as it is caveated that treatment should be applied every four weeks under high flea pressure (same as claims accepted for pioneer fipronil products). Claims against flea eggs, flea larvae, prevention of all flea life stages, and breaking of the flea life cycle are supported for 3 months (90 days).
- 2. Ticks (all stages, including Ticks that may transmit Lyme Disease)
- 3. Mosquitoes
- 4. Chewing Lice
- 5. Aids in Control of Sarcoptic Mange

6. Submitted MRID's are summaries and/or extraneous to data requirements and are rated as supplemental.

Specific Review of Label Claims and Directions:

- 1. Throughout the label, for the mosquito claims related to speed of kill, "Kills mosquitoes within 24 hours for up to 7 days and within 48 hours for up to 28 days", all parenthes must be removed, as this implies optional text for the durations of control.
- 2. Throughout the label, all references to disease claims which are open ended must be revised to only refer to specific diseases that may be transmitted by the targeted pest. For example, all text that can be interpreted as all-inclusive such as "including" prior to a list of diseases must be deleted.



9.7% Fipmed

2.9% Priponentiem

Spot-on for dogs

- Selective Gtation

- Submits prod Chem, Tox(PL, Ett., CAS; Citis CRP data

- Prod Chem

- Acute Tox(PL

- Tox CAS

- EB6



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CREMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

May 15, 2012

MEMORANDUM

Subject:

Name of Pesticide Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

EPA Reg. No. /File Symbol: 2382-RIO

DP Barcode:

DP 398341

Decision No.: Action Code:

459013 R310

PC Codes:

129032 (Pyriproxyfen: 2.9%)

129121 (Fipronil: 9.7%)

From:

Byron T. Backus, Ph.D., Toxicologist Byron T. Ba

To:

Bonaventure Akinlosotu/Richard Gebken RM 10

Insecticide Branch

Registration Division (7505P)

Registrant:

VIRBAC AH, INC.

FORMULATION FROM LABEL:

| Active Ingredient(s): | | by wt. |
|-----------------------|-------|--------|
| 129121 Fipronil | | 9.7% |
| 129032 Pyriproxyfen | | 2.9% |
| Other Ingredient(s): | | 87.4% |
| | TOTAL | 100.0% |

ACTION REQUESTED: The Risk Manager requests:

"For your review: R310. MRID 486969-10 to -14; for a Fipronil + Pyriproxyfen containing Spot-On for dogs. Submits prod chem., tox, efficacy and CAS data..."

BACKGROUND:

The material received for review includes a proposed label, indicating the product is packaged in single-use applicators (1, 3, 6 or 36 applicators per package). Dosage rates are stated to be 0.023 fl. oz. (0.67 mL) "for small dogs and puppies 8 weeks old or older and up to 22.9 lbs," 0.045 fl. oz. (1.34 mL) for dogs weighing 23-44.9 lbs, 0.091 fl. oz. (2.68 mL) for dogs weighing 45-88.9 lbs, and 0.136 fl. oz. (4.02 mL) for dogs weighing 89-132 lbs. The product is to be applied no more frequently than once a month ("Effective monthly control of fleas and ticks," and "Once monthly application." There are five acute toxicity studies (MRID 48696910, acute oral toxicity study in rats; 48696911, acute dermal toxicity study in rats; 48696912, acute eye irritation study in rabbits; 48696913, acute dermal irritation study in rabbits; and 48696914, contact hypersensitivity in albino guinea pigs, Buehler test), and a waiver request for the inhalation toxicity study requirement. In addition, there is a basic CSF, dated October 21, 2011.

COMMENTS AND RECOMMENDATIONS:

- The acute toxicity studies in MRIDs 48696910-48696914 were reviewed by a contractor, Summetic. The resulting DER was reviewed by TRB, and the appropriate revisions, if necessary, were made. It is concluded that these five acute toxicity studies are acceptable, and can be used to support the registration of 2382-RIO.
- 2. TRB has reviewed the acute inhalation toxicity study waiver request, and concludes that, based on the proposed product use and minimal potential inhalation exposure, this study can be waived and the product can be assigned to Toxicity Category IV by the inhalation exposure route.
- 3. Based on the results of the acute toxicity studies, the following is the acute toxicity profile for 2382-RIO (EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS):

| Acute oral toxicity | 111 | Acceptable | MRID 48696910 |
|---------------------------|----------|------------|---------------|
| Acute dermal toxicity | 111 | Acceptable | MRID 48696911 |
| Acute inhalation toxicity | IV | Waived | n/a |
| Primary eye irritation | III | Acceptable | MRID 48696912 |
| Primary dermal irritation | IV | Acceptable | MRID 48696913 |
| Dermal sensitization | Negative | Acceptable | MRID 48696914 |

4. Based on the acute toxicity profile above, the following is the precautionary and first aid labeling for 2382-RIO, as obtained from the TRB Label Review System.

PRODUCT ID #: 002382-00189

PRODUCT NAME: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking,

chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]*

*[Protective eyewear may be specified, if appropriate].

First Aid:

If on skin:

- -Take off contaminated clothing.
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

If swallowed:

- -Call a poison control center or doctor immediately for treatment advice.
- -Have person sip a glass of water if able to swallow.
- -Do not induce vomiting unless told to by a poison control center or doctor.
- -Do not give anything to an unconscious person.

If in eyes:

- -Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- -Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- -Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

5. The basic CSF dated October 21, 2011 for 2382-RIO should be reviewed and accepted by the TRB Chemistry Team.

DATA EVALUATION RECORD

PYRIPROXYFEN AND FIPRONIL [104.11; EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS]

STUDY TYPE: ACUTE ORAL TOXICITY - RAT [OCSPP 870.1100; OECD 425] ACUTE DERMAL TOXICITY - RAT [OCSPP 870.1200; OECD 402] ACUTE EYE IRRITATION - RABBIT [OCSPP 870.2400; OECD 405] ACUTE DERMAL IRRITATION - RABBIT [OCSPP 870.2500; OECD 404] DERMAL SENSITIZATION - GUINEA PIG [OCSPP 870.2600; OECD 406] MRID: 486969-10, 486969-11, 486969-12, 486969-13, and 486969-14

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Summitec Corporation
9724 Kingston Pike, Suite 602
Knoxville, Tennessee 37922

Task Order No. 3-C-10

| | DAMA I EDGO 1- |
|------------|--|
| Signature: | DUMIN LICHEL, ME |
| Date: | APR 16 ZUIZ |
| | TLAMBA C MAISHALL |
| Signature: | Thurners C-marrows |
| Date: | APR 1 6 2012 |
| | Robert W. Rosa |
| Signature: | 1.2000, 10. 1.200 |
| Date: | ADD 1 6 2012 |
| | 1 1 1 1 1 1 1 1 1 1 |
| Signature: | Hingua III. Edmord |
| Date: | APR 1 6 2012 |
| | Date: Signature: Date: Signature: Date: Signature: |

Disclaimer:

This review may have been altered subsequent to the contractor's signatures above.

EPA Reviewer: Byron T. Backus, Ph.D.

Risk Manager (EPA): 10

The following table is the Acute Toxicity Data Evaluation Record (DER) for the five studies submitted for the proposed product, File Symbol 2382-RIO

Date: May 15, 2012

| | .,, | | | ····· | | | |
|--|--------------------------------|--|----------|-----------|--|--|--|
| 1. DP BARCODE: 398341 | 1. DP BARCODE: 398341 | | | | | | |
| 2. PC CODES: 129032 and 129 | 2. PC CODES: 129032 and 129121 | | | | | | |
| 3. CURRENT DATE: May 15 | 3. CURRENT DATE: May 15, 2012 | | | | | | |
| 4. TEST MATERIAL: 104.11; Batch #FMA 11123-1; 9.68% Fipronil and 2.98% Pyriproxyfen | | | | | | | |
| (per certificate of analysis); yello | w odourless | liquid (or colorless to yellowish liquid |); densi | ty: 1.036 | | | |
| g/mL; pH: 4-5 (MRID 48696912 |); expiration | date: November 2011; stored at room | tempera | iture | | | |
| Study/Species/Lab | MRID | Results | Tox | Core | | | |
| Study # /Date | | | Cat | Grade | | | |
| Acute oral toxicity / rat | 48696910 | LD ₅₀ Females = 2000 mg/kg bw | III | Α | | | |
| Harlan Laboratories Ltd. | | [95% PL Confidence interval is 0 | | | | | |
| (ltingen, Switzerland) | | to >20,000] | | | | | |
| Study #D34666 / November 18, | | Four tested (with dosing on day I) | | | | | |
| 2011 | | in accordance with AOT425 | | | | | |
| OCSPP 870.1100; OECD 425 | | StatPgm (assumed sigma=0.5): 1 at | | | | | |
| | | 550 mg/kg, 3 at 2000 mg/kg. | | | | | |
| | | 550 mg/kg: no deaths, abnormal | | | | | |
| | | clinical signs, bw effects, or gross | | | | | |
| NAME OF THE OWNER OF THE OWNER OF THE OWNER OF THE OWNER | | findings. | | | | | |
| | | 2000 mg/kg: 2 deaths (days 6 & 9); | | | | | |
| | | clinical signs: ruffled fur and/or | | | | | |
| | | hunched posture in 2/3 (day 1); | | | | | |
| | | survivor lost wt days 1-8 but had | | | | | |
| | | net gain for the study overall; gross | | | | | |
| | | necropsy findings limited to lung | | | | | |
| | | congestion in both decedents. | | | | | |
| | | Deviation from OECD 425: no | | | | | |
| | | rationale provided for use of | | | | | |
| | | starting dose different from default. | | | | | |

| | , | T | | × |
|--|----------|--|---------|----------|
| Acute dermal toxicity / rat | 48696911 | $LD_{50} > 2000 \text{ mg/kg (both sexes)}$ | III | Α |
| Harlan Laboratories Ltd. | | No deaths, abnormal systemic | | |
| (Itingen, Switzerland) | 1 | clinical signs, or abnormal gross | | |
| Study #D34677 / November 18, | | findings; BW affected: 4/5 males | | |
| 2011 | | and 4/5 females lost weight during | | |
| OCSPP 870.1200; OECD 402 | | days 1-8, all animals gained during | | |
| | <u> </u> | days 8-15 and most had net BW | | |
| | | gain over days 1-15 (1 female had | | |
| ###O | | net loss over days 1-15); local | | |
| | | effects: erythema on 1 male on day | | |
| | | 2 (resolved by day 3), | | |
| | | desquamation and/or focal crusts | | |
| 1 | | on 5/5 males and 4/5 females | | • |
| | | beginning days 2-6 (resolved by | | |
| | ļ | day 15 except desquamation in 1 | | |
| | | male and I female). | | |
| | | Note: It is unclear whether the size | | |
| | | of the dose site really was 10% of | | |
| THOUSENESS AND THE STATE OF THE | | the body surface area (BSA). The | | |
| WANTED TO THE PROPERTY OF THE | | study author stated that application | | |
| | | sites were approximately 10% of | | |
| | | body surface area, but it was also | | |
| | ļ | stated that application sites were | | |
| The state of the s | | covered by a gauze pad measuring | | |
| CHARLES | | ~25 cm², which, according to | | |
| | | standard formulas, would be less | | |
| | | than 10% of the BSA for rats in the | | |
| | | BW range used in this study (193.7- | | |
| | | 276.8). | | |
| | | Deficiency: Systemic clinical signs | | |
| | | data from days 2-15 were omitted | | |
| THE STATE OF THE S | | , , | | |
| A outo inholation toxisity / act | | from the study report. Waiver recommended on basis of | (IV) | W |
| Acute inhalation toxicity / rat | n.a. | | (1 V) | YY |
| | | product use (pet spot-on) and | | |
| Th. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. | 40202010 | minimal inhalation exposure. | 111 | <u> </u> |
| Primary eye irritation / rabbit | 48696912 | Use of anesthetic not mentioned. | 1II | Α |
| Harlan Laboratories Ltd. | | No corneal or iridial effects seen in | | |
| (Itingen, Switzerland) | | any eye at any time point. | | |
| Study #D34688 / November 30, | | Conjunctival redness present in 3/3 | | |
| 2011 | | eyes at 1 hr through 7 days and in | | |
| OCSPP 870.2400; OECD 405 | | 2/3 and 1/3 eyes at 10 and 14 days | | |
| | | post instillation (score=1-2). | | |
| | | Conjunctival discharge seen in 2 | | |
| | | eyes at 1 hour (score=1) and not | | |
| VALUE OF THE PROPERTY OF THE P | | seen thereafter. Slight to moderate | | |
| TRAR PRINCE | | scleral reddening seen in 3 eyes at | | |
| 50020000000000000000000000000000000000 | | 1 hour and in 2 eyes at 24-72 hours. | | |
| C. Miles | | Conjunctivitis scored as "positive" | | |
| | | in 2/3 eyes at 24-48 hrs and in 1/3 | <u></u> | |

| E | | T | ······ | 1 |
|--|----------|--------------------------------------|--------|----------|
| | | eyes at 72 hours. | | |
| | | MMTS=3.33, at 1-48 hours; | | |
| | | Mildly irritating (per Kay and | | ļ |
| | | Calandra). | | |
| 7414444 | | Classified based on resolution of | | |
| ACCOUNTY OF THE PROPERTY OF TH | | "positive" irritation within 7 days | | |
| | | or less. | | |
| Primary dermal irritation / | 48696913 | PDI at 72 hours=0.00 | IV | Α |
| rabbit | | There were no observations of | | |
| Harlan Laboratories Ltd. | | erythema, edema, or other changes | | |
| (Itingen, Switzerland) | | to the skin on any animal at any | | |
| Study #D34690 / November 30, | | time point. | | |
| 2011 | | "Nonirritant" based on US EPA | | |
| OCSPP 870.2500; OECD 404 | | (1988). | | |
| Dermal sensitization / guinea | 48696914 | Tested using Buehler method | | Α |
| pig | · | Induction used 100% | | |
| Harlan Laboratories Ltd. | | concentration; challenge used 75% | | |
| (Fullinsdorf, Switzerland) | | concentration in diethylene glycol | | |
| Study #D34701 / October 27, | | monoethyl ether vehicle. | | |
| 2011 | | No positive dermal reactions on | | |
| OCSPP 870.2600; OECD 406 | | treated or vehicle control animals | | |
| , | | following challenge. | | 900000 |
| | | Not a sensitizer | | |
| | | Deficiencies: Justification not | | |
| | | provided for usage of non-standard | | |
| | | vehicle. It appears that in the | | |
| | | positive control study the testing | | |
| | | lab was not able to identify the | | |
| | | HNIC; two challenge | | |
| | | concentrations (neither of which | | |
| | | was a HNIC) were selected, based, | | |
| | | in part, upon historical results. | | [|
| | | Results of initial challenge were | | AMONG NE |
| | | equivocal, and a re-challenge was | : | |
| | | necessary. "Correct" results were | | |
| | | attained, but the laboratory has not | | |
| | | necessarily demonstrated | | |
| | | proficiency. | | |
| | | projectoy. | | |

 $\label{eq:Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap, W = Waived$



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

BARCODE No.: 398340;

FILE SYMBOL No.: 2382-RIO:

PRODUCT NAME: Effipro Plus Topical Solution for Dogs; DECISION No.: 459013;

Jon 5/15/12

PC Code(s): 129121& 120932; Action Code: R310;

FOOD Use: No

DATE:

May 7, 2012

SUBJECT:

Product Name: Effipro Plus Topical Solution for Dogs

FROM:

Akiva Abramovitch, Ph.D.

Technical Review Branch / RD (7505P)

THROUGH: Shyam Mathur, Ph.D.

Product Chemistry Team Leader

Technical Review Branch/RD (7505P)

TO:

Bonaventure Akinlosotu/Richard Gebken, PM 10

Insecticide Branch/RD (7505C)

Company Name: Virbac

Formulation Type: Spot-On Solution

INTRODUCTION:

The applicant has submitted an application for registration of a new end use product. In support of the registration application, the registrant has submitted product chemistry data corresponding to guideline 830 series, group A & group B (MRIDs 486969-01 through -09). The CSF of the basic formulation (dated 10/21/2011) was submitted along with the product label. TRB has been asked to determine the acceptability of the product chemistry data and the proposed basic CSF dated October 21, 2011.

SUMMARY OF FINDINGS:

| l. | Name of | Active | Ingredient: | Fipronil | (9.7%) |) and | Pyriproxy | yten | (2.99 | 么) | |
|----|---------|--------|-------------|----------|--------|-------|-----------|------|-------|----|--|
|----|---------|--------|-------------|----------|--------|-------|-----------|------|-------|----|--|

2. Has the registrant claimed substantial similarity to a registered product?

| Yes; X No; No; NA; if yes give the registration nu | noer or | L LI | ie chet | ւ բւսասել |
|--|---------|------|---------|-----------|
|--|---------|------|---------|-----------|

| 3. | All the source ma | aterials for the | active ingred | ients are de | erived from t | he registered | sources: |
|----|-------------------|------------------|---------------|--------------|---------------|---------------|--------------|
| | [X] Yes; [] No. | | | | | | added to the |

CSF.

| BARCODE No.: 398340; PRODUCT NAME: Effipro Plus Topical Solution for Dogs; PC Code(s): 129121& 120932; Action Code: R310; | FILE SYMBOL No.: 2382-RIO; DECISION No.: 459013; FOOD Use: No |
|---|---|
| 4. All inert ingredients have been screened by llAB (and foun labeled uses: [X] Yes; [] No. | d to be approved for the proposed |
| 5. Confidential Statement of Formula(s): | |
| [X] Basic Dated: October 21, 2011; | |
| 6. Product label | |
| a. Ingredient statement: Nominal concentration of Al lister (PR Notice 91-2). | d on CSF(s) concur with product label |
| [X] Yes, if not, explain below: | |
| Is the sub statement in compliance with PR Notice 97-6 [X] Yes; [] No; if not, explain below: | (inert ingredient vs other ingredient)? |
| Metallic equivalent: [] Yes [X] NA; Soluble arsenic: [] Yes [X] NA lsomeric ratios: [] Yes [X] NA Acid equivalent: [] Yes [X] NA; {name} acid equ | nivalent = xx % |
| b. Health related sub statements: Product contains? | |
| Petroleum distillate at > 10%: [] Yes [X] No [] Methanol at > 4%: [] Yes [X] No [] Sodium nitrate/Sodium nitrite [] Yes [X] No [] | NA |
| c. Physical chemical hazard statement: Product label requires for: flammability, explosive potential or electric insulates [] Yes [X] No | - v |
| Is the sub statement in compliance with PR Notice 98-6 [] Yes, [] No, [X] NA, if not, explain below: | (Total Release Fogger)? |
| d. Label requires an additional Storage and Disposal statem [] Yes [X] No | ent: |

BARCODE No.: 398340; FILE SYM

FILE SYMBOL No.: 2382-RIO:

PRODUCT NAME: Effipro Plus Topical Solution for Dogs; DECISION No.: 459013;

PC Code(s): 129121& 120932; Action Code: R310; FOOD Use: No

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

| Guideline | | | Data submitted | | TRB's Assessment | | |
|-----------|--------------|---------------------------|----------------|----|---------------------|-----------------|--|
| No. | Study Title | | Yes | No | of Data | MRID Nos. | |
| | Product Ide | ntity & | | | | | |
| 830.1550 | Compositio | n | X | | A | 486969-01 | |
| | Description | of materials used | | | , | | |
| 830.1600 | to produce t | the product | X | | A | 486969-01 | |
| | Description | of formulation | | | | | |
| 830.1650 | process | | X | | A | 486969-01 | |
| | Discussion | on the formation | | | | | |
| 830.1670 | of impuritie | S | X | | A | 486969-01 | |
| | | | | | | 486969-08 and - | |
| 830.1700 | Preliminary | analysis | X | | A | 09 | |
| | Certified | Standard certified Limits | X | | A | | |
| | limits | | | | | | |
| | (158.350) | Proposed Limits | | | NA | | |
| | | Justification for | | | | | |
| 830.1750 | | wider limits | | | NA | 486969-01 | |
| | Enforcemen | nt analytical | | | A (HPLC | 486969-08 and - | |
| 830.1800 | method | | X | | method) | 09 | |

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable

BARCODE No.: 398340; FILE SYMBOL No.: 2382-RIO;

PRODUCT NAME: Effipro Plus Topical Solution for Dogs; DECISION No.: 459013;

PC Code(s): 129121& 120932; Action Code: R310; FOOD Use: No

8. Group **B**:

| Guideline No. | Study Title | Value or Qualitative Description | TRB's Assessment of Data | MRID Nos. |
|------------------|-----------------|--|--------------------------|-----------|
| 830.6303 | Physical State | Colorless liquid with sweet odor | Α | 486969-02 |
| 830.6315 | Flammability | 94.3°C flashpoint | A | 486969-04 |
| 830.6316 | Explodability | NA, not considered to be potentially explosive | A | 486969-02 |
| 830.7000 | рН | 5.95 1% solution at 23 C | A | 486969-05 |
| 830.7300 | Density (units) | 1.032 g/cm ³ | A | 486969-07 |

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress, U = Upgradeable

CONCLUSIONS:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

- 1. The proposed CSF for the basic formulation dated October 21 2011 is acceptable
- 2. The data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1650 (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.
- 3. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidation/reduction), 830.6315 (flammability), 830.6316 (explodability), 830.7000 (pH), 830.7100 (viscosity), and 830.7300 (density) are acceptable.
- 4. The storage stability (guideline 830.6317) and corrosion characteristics (guideline 830.6320) studies were not submitted. These physical/chemical properties are required and it is recommended that observations should be made at 0, 3, 6, 9, and 12 month intervals.
- 5. The proposed label was screened as it pertains to the product chemistry requirements. The review of the proposed label and uses are the purview of the RM team.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

June 7, 2012

MEMORANDUM

Subject:

Name of Pesticide Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

EPA Reg. No. /File Symbol: 2382-RIO

DP Barcode:

DP 398344 459013

Decision No.: Action Code:

R310

PC Codes:

129032 (Pyriproxyfen: 2.9%)

129121 (Fipronil: 9.7%)

From:

Byron T. Backus, Ph.D., Toxicologist

Technical Review Branch

Registration Division (7505P)

To:

Byra T. B - D Jone 7, 2012 Maslur Teambearder Texicalogy Bonaventure Akinlosotu/Richard Gebken RM 10

Insecticide Branch

Registration Division (7505P)

Registrant:

VIRBAC AH, INC.

FORMULATION FROM LABEL:

| Active Ingredient(s): | | <u>by wt.</u> |
|-----------------------|-------|---------------|
| 12912 I Fipronil | | 9.7% |
| 129032 Pyriproxyfen | | 2.9% |
| Other Ingredient(s): | | 87.4% |
| | TOTAL | 100.0% |

ACTION REQUESTED: The Risk Manager requests:

"For your review: R310. MRID 48696916; for a Fipronil + Pyriproxyfen containing Spot-On for dogs. Submits prod chem., tox, efficacy and CAS data..."

BACKGROUND:

The material received for review includes a proposed label, indicating the product is packaged in single-use applicators (1, 3, 6 or 36 applicators per package). Dosage rates are stated to be 0.023 fl. oz. (0.67 mL) "for small dogs and puppies 8 weeks old or older and up to 22.9 lbs," 0.045 fl. oz. (1.34 mL) for dogs weighing 23-44.9 lbs, 0.091 fl. oz. (2.68 mL) for dogs weighing 45-88.9 lbs, and 0.136 fl. oz. (4.02 mL) for dogs weighing 89-132 lbs. The product is to be applied no more frequently than once a month ("Effective monthly control of fleas and ticks," and "Once monthly application." There is a data matrix (dated December 20, 2011) which cites 12 studies to satisfy the companion animal safety data requirement (MRIDs 43444905, 43577711, 43863802, 43121110, 43121111, 45620507, 43396408, 43612601, 44900902, 44900903, 42178309, and "new submission" [presumably the material in MRID 48696916, which consists of summaries of several previously reviewed companion animal safety and other studies; OPPIN indicates no studies have been submitted for 2382-RIO] from Virbac.

COMMENTS AND RECOMMENDATIONS:

- 1. The following are review summaries of the eleven studies (the 12 indicated above less the material in MRID 48696916) that have been cited to satisfy the 870.7200 data requirement to support the registration of 2382-RIO.
- MRID 43444905: Schwartz, E. (1994) Domestic Animal Safety Study of RM1601C Topical Spray (Frontline Spray Treatment) in Juvenile Dogs: Lab Project Number: 94423: PS-232DAS. Unpublished study prepared by White Eagle Toxicology Labs. 171 p. [according to OPPIN the products supported by this study are 65331-1 and 65331-EUP-1; DERs for this study are in TXRs 0011677 and 0011764; Groups of 4 or 6 beagles (~8 weeks old) per sex received single applications of RM 1601C Topical Spray [0.25% w/v fipronil = 0.29% w/w fipronil] at dosages of 6 mL/kg (1X recommended dose) or 30 mL/kg (5X). A control group of 4/sex was treated with the vehicle at 30 mL/kg. This study was upgraded to acceptable in TXR 0011764].
- MRID 43577711: Walker, K. (1995) Discussion in Support of Bridging Domestic Animal Safety Data
 on Frontline Spray Treatment to Frontline Spot Treatment Data Package. Unpublished study prepared
 by Rhone Merieux, Inc. 6 p. [According to OPPIN the product supported is 65331-EUP-E; this is not
 an actual study, but an argument as to why there is justification for linking the spot-on product
 containing ~10% fipronil to the data base of an existing product (Frontline® Spray Treatment, 0.25%
 w/v fipronil)].
- MRID 43863802: Powell, L.; Paffett, R. (1995) Domestic Animal Safety Study by Topical Administration to Dogs: Fipronil Spot Treatment (RM 1601E): Lab Project Number: MRX 23/950406. Unpublished study prepared by Huntingdon Research Centre, Ltd. 219 p. [According to OPPIN the product supported was 65331-EUP-E; from TXR 0051187: "...4 male and 4 female pure-bred beagle dogs (approximately 10 weeks of age) were administered a single topical treatment of RM1601E/62 (9.7% fipronil) at either 1X, 3X or 5X the recommended dose (0.133 mg/kg/spot) once every month for a total of 6 treatments... 4 male and 4 female dogs served as a control group and were treated with the formulation vehicle at 5X the recommended dosage. A similar group served as an untreated control... The study demonstrated that RM1601E/62 (9.7% fipronil) has at least a 5X margin of safety

in dogs greater than 10 weeks of age. The product label should state that there may be temporary irritation after application." The study was classified as acceptable].

- MRID 43121110: Arnaud, J.; Consalvi, P. (1993) Assessment of Tolerance of a 0.25% RM 1601 Spray Formulation in Dogs at 3, 9, and 15 ml/kg When Applied 6 times to the Haircoat at 28 Day Intervals: Revised: Lab Project Number CLI138. Unpublished study prepared by Rhone Merieux, Inc. 69 p. [according to OPPIN the product supported by this study is 65331-EUP-1; a DER for this study is in TXR 0010923; groups of 3M & 3F beagle dogs were topically administered 6 treatments of 0.25% fipronil at dosages of either 0, 3, 9 or 15 mL/kg (0, 7.5, 22.5 and 37.5 mg fipronil/kg, respectively) at 28-day intervals. The proposed recommended dose for the 0.25% product was 3 to 6 mL/kg; 0.67 mL of a 9.7% fipronil product applied to a 5 kg dog would be equivalent to a dosage of 13 mg fipronil/kg. From TXR 0010923: "Classification: Unacceptable because: 1) the highest dosage level was not 5X the highest recommended dose; and 2) the study was not conducted in compliance with the GLP regulations].
- MRID 43121111: Arnaud, J.; Consalvi, P. (1993) Domestic Animal Safety: Assessment of the Tolerance of a 0.25% RM 1601 Spray in Nursing Puppies Administered Twice at a 28 Day Interval at a Dose Rate of 6 ml/kg: Revised: Lab Project Number CLI 180. Unpublished study prepared by Rhone Merieux, Inc. 32 p. [According to OPPIN the product supported by this study is 65331-EUP-1; a DER for this study is in TXR 0010923; a total of 27 male and 21 female nursing puppies (9 litters of either beagle, spaniel or griffon breeds) topically received two treatments of 0.25% formulation at a dosage of 6 mL/kg (proposed recommended dosage = 6 mL/kg) with 28 days between the treatments. The dams of the litters were treated at the same dosage. Twenty-six male and 15 females served as untreated controls. Six treated puppies, including four from the same spaniel litter, died before weaning and another died after weaning. Parvovirus was isolated from the spaniel litter. One control puppy died; there was no statistical difference in mortality between the groups. Growth rates were either comparable to or exceeded the applicable control group for the beagle and griffon breeds, but were lower for the spaniel (this lower growth rate may have been from the parvovirus infection). Classification: Unacceptable because: 1) the study was conducted with nursing rather than weaned puppies; 2) the highest dosage level was not at 5X the recommended dose; 3) the study was not conducted in compliance with GLP regulations].
- MRID 45620507: Godin, C.; Alva, R. (2000) ML-2,095,988 509T/Dog/Solution/Topical/Safety/ Tolerance/Reproduction, Reactions: Final Report: Lab Project Number: PR&D 0020201: WEL 99885: PR&D 00202. Unpublished study prepared by White Eagle Toxicology Laboratory. 123 p. [From OPPIN the product supported by this study is 65331-5; the review of this study is in TXR 5008387: In a special (reproductive) companion animal safety study a topical formulation containing 10% w/v fipronil and 9% w/v (S)-methoprene was administered at 0X (Group 1; sham-treated controls), 1X or 0.133 mL/kg (Group 2) and 3X or 0.399 ml/kg (Group 3) to groups of 12 adult female beagle dogs (bitches) prior to and during pregnancy, through parturition and to weaning of the puppies. The only dose-related effects observed in bitches were pink skin at the application site on days of treatment (recorded 15 times in Group 2, 37 times in Group 3), and pink skin at the application site on the day following treatment (3 times in Group 3). There was no indication of an adverse effect on any reproductive parameters (including gestation index, incidence of cesarean section, incidences of stillborn pups, incidences of pups dying between birth and weaning). There were no significant differences between puppies from the 3 groups with respect to physiological parameters (mean body

weights, mean rectal temperatures, mean respiratory rates, mean heart rates) measured on post-parturition days 14, 28 and 42.

Although no dogs were dosed at 5X level, and no blood was taken for clinical chemistry and hematology measurements, the purpose of this study was to allow a label claim on breeding, pregnant and lactating bitches. TRB has previously reviewed a companion animal (dog) study for this formulation which included a 5X dosage group and measurements of clinical chemistry and hematology parameters. This study is classified as acceptable. The findings of this study are adequate to support the use of EPA Reg. Nos. 65331-3 and 65331-5 at the specified label use rates (varying according to the weight of dog) at 28-day intervals on breeding, pregnant and lactating bitches].

- MRID 43396408: Pennington, R.; Clymer, B. (1994) Study Report for the Target Animal Safety Evaluation of ECTO Flea and Tick Insecticide with IGR on Dogs: Lab Project Number: A-94-01-F701-007: 278-94-59: F701R09. Unpublished study prepared by CALV, Inc. & CRC. 28 p. [From OPPIN the product supported by this study is 67505-3; the review of this study is in TXR 0011565: 4 groups of mixed breed/beagle adults and puppies were exposed to 0, vehicle control (at 5X) or a formulation containing 45% permethrin and 5% pyriproxyfen at weekly intervals for a total of two applications. At 1X and above, slight to severe dermal reactions were observed. In the vehicle treated group 5/6 animals exhibited mild to severe dermal reactions which were as severe as in the 5X treated group. The study did not demonstrate a 3-5 fold safety factor between use as directed and dermal reactions].
- MRID 43612601: Pennington, R.; Kuhn, J. (1995) Report for the Target Animal Safety Evaluation of ECTO Flea and Tick Insecticide with IGR on Dogs: Lab Project Number: A-93-01-F701-027: 1617-94: F701R14. Unpublished study prepared by Ecto Development Corp. and Stillmeadow, Inc. 24 p. [From OPPIN the product supported by this study is 67505-3; the review of this study is in TXR 0011865: Adult dogs and puppies (1-2 subjects, ~3 months) 6/dose group were dosed once as control (untreated), 1X and 5X the label dosage rate of Ecto Flea and Tick Insecticide with IGR and followed for 31 days. No reactions to treatment were noted. The study demonstrated a 5X safety factor between use as directed and a dose level not resulting in toxicity or irritation. The study is classified as acceptable to support the use of this product (EPA Reg. No. 67505-3) on adult dogs (>6 months of age) only].
- MRID 44900902: Fabreguettes, C. (1998) Tolerance in 3 Month Old Puppies: Pyriproxyfen 2% Spot On For Dogs: Lab Project Number: CIT 15615TSC. Unpublished study prepared by Centre International de Toxicologie. 253 p. [From OPPIN the product supported by this study is 2382-RTU; Pyriproxyfen (2%) was topically applied to groups of three male and three female beagle dogs (3 months old; mean body weight of males 4.4 kg; females 3.9 kg) for two periods of three consecutive days each (days 1, 2, and 3 and then days 19, 20 and 21) at 0.6 mL (1X), 1.2 mL (2X), and 1.8 mL (3X) of the recommended therapeutic dose level, followed by a 15-day observation period. Controls were treated with 1.8 mL of excipient. No animals died during the study and there were no treatment related clinical signs. No changes in body weight, food consumption, water consumption, hematology, clinical chemistry, or urinalysis were treatment related. Electrocardiographic and ophthalmological examinations did not reveal any abnormalities in the treated animals. Microscopic examination did not reveal any treatment-related effects. Classification: Unacceptable; Deviations include not testing six animals/sex/group, and not testing at a dose of 5X].

- MRID 44900903: Fabreguettes, C. (1999) Tolerance in 1 Month Old Puppies: Pyriproxyfen 2% Spot On For Dogs: Lab Project Number: CIT 15644TSC. Unpublished study prepared by Centre International de Toxicologie. 194 p. [From OPPIN the product supported by this study is 2382-RTU; Pyriproxyfen 2% was topically applied to groups of three male and three female beagle dogs (1 month old) for two periods of three consecutive days (days 1, 2, and 3 and then days 19, 20 and 21) at 0.6 mL (1X) and 1.8 mL (3X) of the recommended therapeutic dose level, followed by a 15-day observation period. Controls were treated with 1.8 mL of excipient. No animals died during the study and there were no treatment related clinical signs. Body weight gain was slightly reduced in treated animals, but not to statistically significant levels. Changes in hematology and clinical chemistry parameters were sporadic and did not appear to be related to treatment. Electrocardiographic and ophthalmological examinations revealed no abnormalities in the treated animals. Macroscopic and microscopic examination revealed no treatment related changes, although serous contents were observed in the abdominal cavity in 1/6 animals in the low dose group and 4/6 animals in the high dose group (but not in any control animals). The product labeling indicates that the dose is 0.021 fl. oz or 0.6 mL, and the application instructions state that the product should be reapplied every three months and should not be applied to puppies less than 1 month old. In this study the product was applied at 1X and 3X dose levels once per day for three consecutive days and again for another 3-day period 19-21 days after the first treatment. Classification: Unacceptable; Deviations include not testing six animals/sex/group, and not testing at a dose of 5X].
- MRID 42178309: Chapman, E. (1991) S31183: Toxicity Study by Oral (Capsule) Administration to Beagle Dogs for 52 Weeks (Sumilarv Technical Grade): Lab Project Number: 91/0776. Unpublished study prepared by Life Science Research Ltd. 320 p. [Dose levels tested: 0, 30, 100, 300 and 1000 mg/kg/day in the diet for 54 weeks; study demonstrates a low level of toxicity associated with chronic exposure to Pyriproxyfen; the dietary NOEL was 100 mg/kg/day].
- 2. After comparing the CSFs for 2382-RIO and 65331-3, TRB concludes that the studies cited by the registrant to satisfy the 870.7200 data requirements adequately support the use of 2382-RIO at the indicated dosage rates (0.023 fl. oz. or 0.67 mL on dogs up to 22.9 lbs; 0.045 fl. oz. or 1.34 mL on dogs 23-44.9 lbs; 0.091 fl. oz. or 2.68 mL on dogs 45-88.9 lbs; 0.136 fl. oz. or 4.02 mL on dogs 89-132 lbs) on adult dogs and puppies of 8 weeks of age and older on a once-a-month (or every 4 weeks) basis.
- 3. TRB also concludes that because of the presence of 2.9% pyriproxyfen in 2382-RIO the study in MRID 45620507 cannot be used to support the use of 2382-RIO on breeding, pregnant and/or lactating bitches [although this claim does not appear on the proposed label dated December 14, 2011]. Labeling must then also include the statement: "Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals" as indicated in PR Notice 96-6.



December 20, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RIC

Subject:

EFFIPRO® PLUS Topical Solution for Dogs (EPA File Symbol 2382-TBA);

New Product Application.

Dear Mr. Gebken,

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX 76137, (Company Number 2382)) is hereby submitting an application to register the spot-on pesticide product EFFIPRO® PLUS Topical Solution for Dogs.

This product contains the active ingredients fiprouil and pyriproxifen and is intended to control fleas, ticks, mosquitoes, and other pests on dogs only.

Pyriproxyfen itself is registered alone and in combination with other active ingredients in numerous end use products for spot-on insect growth regulator use on dogs.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Offer to Pay letters are being sent to the submitters of data cited in Virbac's application that were originally submitted within the past 15 years.

Below is a list of the components included with this application:

- 1. Cover Letter;
- 2. Transmittal Document;
- 3. Application for Pesticide Form 8570-1;
- 4. Confidential Statement of Formula-2 Copies;
- 5. Data Matrix Form 8570-4; (EUP and TGAI);
- 6. Certification of Data Citation Form 8570-34;
- 7. Proposed Label 5 copies;
- 8. 3 copies of bound PR 86-5 compliant study reports supporting registration;
- 9. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
- 10. Letter of Self-certification of Child-Resistant Packaging;
- 11. Formulator's Exemption Form 8570-27; and
- 12. Copy of PRIA Check for category R-310 (\$4807).

Child-Resistant Packaging

EFFIPRO® PLUS Topical Solution for Dogs and will be marketed in single dose unit applicators in packages of 1, 3, 6, and 36. These single dose applicators for the 0.67 ml, 1.34 ml, 2.68 ml, and 4.02 ml dose sizes have been previously tested, and CRP certification has been accepted by EPA. All relevant test data supporting self-certification have been reviewed are and cited in the attached Data Matrix. A self-certification letter is also attached.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this product. Consequently, please find a copy of one previously submitted check in the amount of \$4807 to cover the PRIA fee.

Should you have any questions about this application package, please do not liesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

Craig Parks, MS, DVM

Craig take

Vice President, Research & Development

Virbac Animal Health, Inc.

Attachments

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac, Inc. (EPA Company Number 2382) P.O. Box 162059 Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use pro namely EFFIPRO® PLUS Topical Solution for Dogs. Effipro® EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredients Fipronil and Pyriproxyfen.

SUBMITTAL DATE:

December 20, 2011

| Volume | Study Title | MRID No. |
|--------|---|----------|
| Freez | Administrative Materials Effipro® Plus Topical Solution for Dogs | |
| | Group A Product Chemistry | |
| 2 | OPPTS 830.1550, 830.1750, 830.1600, 830.1620, 830.1650, 830.1670 EFFIPRO® PLUS Topical Solution for Dogs | 48696901 |
| | Group B Product Chemistry | |
| 3 | OPPTS 830.6302, 830.6303, 830.6304 Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)" | 48696902 |
| 4 | OPPTS 830.6314 Determination of Oxidation / Reduction (Chemical Incompatibility) | 48696903 |
| 5 | OPPTS 830.6315 Determination of the Physico-Chemical Property "Flash Point" | 48696904 |
| 6 | OPPTS 830.7000 Determination of the Physico-Chemical Property "pH" | 48696905 |
| 7 | OPPTS 830.7100 Determination of Physico-Chemical Property "Viscosity" | 48696906 |
| 8 | OPPTS 830.7300 Determination of the Physico-Chemical Property "Relative Density" | 48696907 |

| Volume | Study Title | MRID No. |
|--------|---|---|
| 9 | OPPTS 830.1700, 830.1800 | |
| | Quantification of the Active Ingredients Fipronil and Pyriproxyfen | 48696908 |
| | in Five Batches by Validated Methods | |
| 10 | OPPTS 830.1800 | |
| | Enforcement Analytical Method – Quantification of the Active | 48696909 |
| | Ingredients Fipronil and Pyriproxyfen | |
| | Acute Toxicity | |
| 11 | OPPTS 870, 1100 | 40000040 |
| | Acute Oral Toxicity Study in Rats – Up-and-Down-Procedure | 48696910 |
| 12 | OPPTS 870.1200 | |
| | Acute Dermal Toxicity Study in Rats | 48696911 |
| 13 | OPPTS 870.2400 | 48696912 |
| | Acute Eye Irritation Study in Rabbits | +409091Z |
| 14 | OPPTS 870.2500 | 48696913 |
| | Acute Dermal Irritation Study in Rabbits | |
| 15 | OPPTS 870.2600 | 48696914 |
| | Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test | *************************************** |
| | Product Performance | |
| 16 | OPPTS 810.3300 | |
| | Summary of Efficacy Data for EFFIPRO® PLUS Topical Solution | 48696915 |
| | for Dogs | |
| | Product Safety | |
| 17 | OPPTS 870.7200 | 4000 |
| | Summary of Companion Animal Safety Data for EFFIPRO® PLUS Topical Solution for Dogs | 48696916 |

DATA PACKAGE BEAN SHEET

Date: 02-Feb-2012 Page 1 of 2

* * * Registration Information * * *

Decision #: 459013

DP #: (398342)

PRIA

Parent DP #:

Submission #: 908748

E-Sub #:

Registration: 2382-RIO - EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS Company: 2382 - VIRBAC AH, INC. Risk Manager: RM t0 - Richard Gebken - (703) 305-670 t Room# PY1 S-7237

Calculated Due Date: 10-Jul-2012 Edited Due Date: Sent Date: Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT; NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 129032, Pyriproxyfen(2.9%)

* * * Data Package Information * * *

| Expedite: | ○ Yes | ● No | | Date Sent: | 02-Feb-201 | ·- <u>-</u> | Due Back: | |
|----------------|----------|--------------|-----------------|------------|------------|-------------|---|--|
| DP Ingredient: | 129032, | Pyriproxyfen | | | | | *************************************** | |
| | 129121, | Fipronil | | | | | | |
| DP Title: | efficacy | ·// | | | | | | |
| CSF Included: | Yes | ○ No | Label Included: | Yes 🔾 | No F | arent DP #: | | |

Assigned To Date in Date Out Last Possible Science Due Date: 10-Jun-2012 Organization: RD / IB Team Name: Efficacy (IB) Science Due Date: Reviewer Name: Sub Data Package Due Date: Contractor Name:

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

For your review: R310

MRID 48696915; for a Fipronil + Pyriproxyfen containing Spot-On for dogs.

Submits prodichem, tox, efficacy and CAS data; Cites CRP data.

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

t29121, Fipronii(9.7%)

Thanks, B.A.

Page 2

DP#: (398342)

* * * Studies Sent for Review * * *

Decision#: (459013)

MRID Status

Citation Reference

Willard, I. (2011) Summary of Efficacy Data for Dogs (Fipronii 9.7% and Pyriproxyfen 2.9% End Use Product). Project Number: VIRBAC/104/11/2. Unpublished study prepared by Isa Vet Biosciences 12p.

55



December 20, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject:

EFFIPRO® PLUS Topical Solution for Dogs (EPA File Symbol 2382-TBA);

New Product Application.

Dear Mr. Gebken,

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX 76137, (Company Number 2382)) is hereby submitting an application to register the spot-on pesticide product EFFIPRO® PLUS Topical Solution for Dogs.

This product contains the active ingredients fipronil and pyriproxifen and is intended to control fleas, ticks, mosquitoes, and other pests on dogs only.

Pyriproxyfen itself is registered alone and in combination with other active ingredients in numerous end use products for spot-on insect growth regulator use on dogs.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Offer to Pay letters are being sent to the submitters of data cited in Virbac's application that were originally submitted within the past 15 years.

Below is a list of the components included with this application:

- 1. Cover Letter;
- 2. Transmittal Document;
- 3. Application for Pesticide Form 8570-1;
- 4. Confidential Statement of Formula-2 Copies;
- 5. Data Matrix Form 8570-4; (EUP and TGAI);
- 6. Certification of Data Citation Form 8570-34;
- 7. Proposed Label 5 copies;
- 8. 3 copies of bound PR 86-5 compliant study reports supporting registration;
- 9. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
- 10. Letter of Self-certification of Child-Resistant Packaging;
- 11. Formulator's Exemption Form 8570-27; and
- 12. Copy of PRIA Check for category R-310 (\$4807).

Child-Resistant Packaging

EFFIPRO® PLUS Topical Solution for Dogs and will be marketed in single dose unit applicators in packages of 1, 3, 6, and 36. These single dose applicators for the 0.67 ml, 1.34 ml, 2.68 ml, and 4.02 ml dose sizes have been previously tested, and CRP certification has been accepted by EPA. All relevant test data supporting self-certification have been reviewed are and cited in the attached Data Matrix. A self-certification letter is also attached.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this product. Consequently, please find a copy of one previously submitted check in the amount of \$4807 to cover the PRIA fee

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

Craig Parks, MS, DVM

Craig take

Vice President, Research & Development

Virbac Animal Health, Inc.

Attachments

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac, Inc. (EPA Company Number 2382) P.O. Box 162059 Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use pro namely EFFIPRO® PLUS Topical Solution for Dogs. Effipro® EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredients Fipronil and Pyriproxyfen.

SUBMITTAL DATE:

December 20, 2011

| Volume | Study Title | MRID No. |
|--------|---|----------|
| 1 | Administrative Materials Effipro® Plus Topical Solution for Dogs | |
| | Group A Product Chemistry | |
| 2 | OPPTS 830.1550, 830.1750, 830.1600, 830.1620, 830.1650, 830.1670 EFFIPRO® PLUS Topical Solution for Dogs | 48696901 |
| | Group B Product Chemistry | |
| 3 | OPPTS 830.6302, 830.6303, 830.6304 Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)" | 48696902 |
| 4 | OPPTS 830.6314 Determination of Oxidation / Reduction (Chemical Incompatibility) | 48696903 |
| 5 | OPPTS 830.6315 Determination of the Physico-Chemical Property "Flash Point" | 48696904 |
| 6 | OPPTS 830.7000 Determination of the Physico-Chemical Property "pH" | 48696905 |
| 7 | OPPTS 830.7100 Determination of Physico-Chemical Property "Viscosity" | 48696906 |
| 8 | OPPTS 830.7300 Determination of the Physico-Chemical Property "Relative Density" | 48696907 |

| Volume | Study Title | MRID No. |
|--------|---|----------|
| 9 | OPPTS 830.1700, 830.1800 | |
| | Quantification of the Active Ingredients Fipronil and Pyriproxyfen | 48696908 |
| | in Five Batches by Validated Methods | |
| 10 | OPPTS 830.1800 | |
| | Enforcement Analytical Method – Quantification of the Active | 48696909 |
| | Ingredients Fipronil and Pyriproxyfen | |
| | Acute Toxicity | |
| 11 | OPPTS 870, 1100 | 40000040 |
| | Acute Oral Toxicity Study in Rats - Up-and-Down-Procedure | 48696910 |
| 12 | OPPTS 870.1200 | |
| | Acute Dermal Toxicity Study in Rats | 48696911 |
| 13 | OPPTS 870.2400 | 4850cc45 |
| | Acute Eye Irritation Study in Rabbits | 48696912 |
| 14 | OPPTS 870.2500 | 48696913 |
| | Acute Dermal Irritation Study in Rabbits | 10000010 |
| 15 | OPPTS 870.2600 | 48696914 |
| | Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test | 70030314 |
| | Product Performance | |
| 16 | OPPTS 810.3300 | |
| | Summary of Efficacy Data for EFFIPRO® PLUS Topical Solution | 48696915 |
| | for Dogs | |
| | Product Safety | |
| 17 | OPPTS 870.7200 | |
| | Summary of Companion Animal Safety Data for EFFIPRO® PLUS Topical Solution for Dogs | 48696916 |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. WASHINGTON, D.C. 20460

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| | \mathbf{D}_{A} | ATA MATRIX | | | |
|--------------------------------|--|-----------------|---|--------------|------------------------------|
| Date: December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | |
| | pplicant's/Registrant's Name & Address | | | | |
| Virbae AH, Inc. | | | | | 1 |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUT | ION FOR DOGS | 1 |
| Fort Worth TX 76161 | | | | | |
| Ingredient: Fipronil, Pyriprox | | L MRID N | 0.5 | | 1 37-4- |
| Guideline Reference Number | | MRID Number | Submitter | Status | Note |
| Product Chemistry Test | | The Color | | | |
| 830,1550 | Product Identity and Composition | New Submission | Virbac AH, Inc. | OWN | |
| 830.1600 | Description of Materials Used | New Submission | Virbac AH, Inc. | OWN | |
| 830,1620 | Description of Production Process | New Submission | Virbac AH, Inc. | OWN | <u> </u> |
| 830.1650 | Description of Formulation Process | New Submission | Virbac AH, Inc. | OWN | |
| 830.1670 | Description of Formation of Impurities | New Submission | Virbac AH, Inc. | OWN | |
| 830.1700 | 5-Batch Analysis | New Submission | Virbac AH, Inc. | OWN | |
| 830.1750 | Certified Limits | New Submission | Virbae AH, Inc. | OWN | |
| 830.1800 | Analytical Method | New Submission | Virbae AH, Inc. | OWN | |
| 830.6302 | Color | New Submission | Virbac AH, Inc. | OWN | |
| 830.6303 | Physical State | New Submission | Virbac Al-l, Inc. | OWN | |
| 830.6304 | Odor | New Submission | Virbae AH, Inc. | OWN | |
| 830.6313 | Metal Stability | | Virbac AH, Inc. | NR | |
| 830.6314 | Oxidation/reduction | New Submission | Virbac AH, Inc. | OWN | |
| 830.6315 | Flammability | New Submission | Virbac AH, Inc. | OWN | |
| 830.6316 | Explodability | ····· | Virbac AH, Inc. | NR | |
| 830.6317 | Storage stability | To be conducted | Virbac AH, Inc. | OWN | |
| Signature Craig Rache | | | Name and Title Craig Parks Vice President, Research & Develop | ment | Date December 20, 2011 |

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-9060



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. WASHINGTON, D.C. 20460

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| | DA | TA MATRIX | | | |
|--------------------------------------|--|--|--|--|----------|
| Date December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | |
| Applicant's/Registrant's Name & A | ddress | | Product: | ······································ | |
| Virbac AH, Inc | | | | | |
| PO Box 162059 Fort Worth TX 76161 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | OR DOGS | |
| tugredient: Fipronil, Pyriproxyfen | | ······································ | | | |
| Guideline Reference Number | Guideline Study Name | MR(D Number | Subnütter | Status | Note |
| 830.7100 | Viscosity | New Submission | Virbac AH, Inc. | OWN | |
| 830.6319 | Miscibility | | Virbac AH, Inc. | NR | |
| 830.6320 | Corrosion characteristics | To be conducted | Virbac AH, Inc. | OWN | |
| 830.6321 | Dielectric breakdown voltage | | Virbac AH, Inc. | NR | |
| 830,7000 | pH | New Submission | Virbac AH, Inc. | OWN | |
| 830,7300 | Density, bulk density, or specific gravity | New Submission | Virbac AH, Inc. | OWN | |
| 830.7320 | Particle Size distribution | | Virbac AH, Inc. | NR | |
| 40 CFR 158.340 Toxicology D | | | | | |
| 870.1100 | Acute oral toxicity | New Submission | Virbac AH, Inc. | OWN | |
| 870.1200 | Acute dermal toxicity | New Submission | Virbac AH, Inc. | OWN | |
| 870,1300 | Acute inhalation toxicity | Waiver requested | Virbac AH, Inc. | | |
| 870,2400 | Primary eye irritation | New Submission | Virbac AH, Inc. | OWN | |
| 870.2500 | Primary dermal irritation | New Submission | Virbac AH, Inc. | OWN | |
| 870.2600 | Dermal sensitization | New Submission | Virbac All, Inc. | OWN | |
| Signature | | | Name and Title | | Date |
| 1 1 | | | Craig Parks | | December |
| Cray Kah | | | Vice President, Research & Development | | 20, 2011 |
| · rung. | | | | | ļ |
| | | | | | 1 |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. WASHINGTON, D.C. 20460

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| | | DATA MATRIX | | | |
|--------------------------------------|----------------------|----------------|---|----------|----------------------------------|
| Date: December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | |
| Applicant's/Registrant's Name & A | ddress | | Product: | | |
| Virbae AH, Inc | | | | | |
| PO Box 162059 Fort Worth TX 76161 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | OR DOGS | |
| Ingredient: Fipronil, Pyriproxyfen | | | <u></u> | | <u></u> |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Efficacy and Safety Data | | | | - Ciaias | 11010 |
| 870.7200 | Dog safety | 43444905 | Merial | OLD | <u> </u> |
| 870.7200 | Dog safety | 43577711 | Merial | OLD | |
| 870.7200 | Dog safety | 43863802 | Merial | OLD | |
| 870.7200 | Dog safety | 43121110 | Merial | OLD | |
| 870.7200 | Dog safely | 43121111 | Merial | OLD | |
| 870.7200 | Dog safcty | 45620507 | Merial | PAY | |
| 870.7200 | Dog safety | 43396408 | Ecto Development Corporation | OLD | |
| 870.7200 | Dog safety | 43612601 | Ecto Development Corporation | OLD | |
| 870.7200 | Dog safety | 44900902 | Virbac AH, Inc. | OWN | |
| 870,7200 | Dog safety | 44900903 | Virbac AH, Inc. | OWN | |
| 870,7200 | Dog safety | 42178309 | Sumitomo Chemical Company, Ltd. | OLD | |
| 870.7200 | Dog safety | New submission | Virbae AH, Inc. | OWN | |
| 810.3300 | Efficacy | 43121114 | Merial | OLD | |
| 810.3300 | Efficacy | 43121115 | Merial | OLD | |
| 810.3300 | Efficacy | 43121116 | Merial | OLD | |
| 810.3300 | Efficacy | 43121117 | Merial | OLD | |
| 810.3300 | Efficacy | 43121118 | Merial | OLD | |
| 810.3300 | Efficacy | 43121119 | Merial | OLD | |
| 810.3300 | Efficacy | 43121120 | Merial | OLD | 1 |
| Signature Conj Rah | | | Name and Title Craig Parks Vice President, Research & Development | | Date Documber 20, 2011 |

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. WASHINGTON, D.C. 20460

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| | | DATA MATRIX | | | |
|--------------------------------------|----------------------|--|---|--------|-----------------------------|
| Date: December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | Page 4 of 9 |
| Applicant's/Registram's Name & A | ddress | | Product: | | |
| Virbae AH, Inc | | | | | |
| PO Box 162059 Fort Worth TX 76161 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | R DOGS | |
| Ingredient: Fipronil, Pyriproxyfen | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Efficacy and Safety Data | | | | | |
| | | | | | |
| 810.3300 | Efficacy | 43121121 | Merial | OLD | |
| 810,3300 | Efficacy | 43121122 | Merial | OLD | |
| 810.3300 | Efficacy | 43444901 | Merial | OLD | |
| 810.3300 | Efficacy | 43577701 | Merial | OLD | |
| 810.3300 | Efficacy | 43577712 | Mcrial | OLD | |
| 810.3300 | Efficacy | 43577713 | Merial | OLD | |
| 810.3300 | Efficacy | 43951701 | Merial | OLD | |
| 810.3300 | Efficacy | 44088901 | Merial | OLD | |
| 810.3300 | Efficacy | 46006002 | Wellmark International | PUBL | |
| 810,3300 | Efficacy | 44900904 | Virbac AH, Inc. | OWN | |
| 810.3300 | Efficacy | 45020601 | Virbac AH, Inc. | OWN | |
| 810.3300 | Efficacy | Pending; submitted with Effipro Plus Cat Application | | OWN | |
| 810.3300 | Efficacy | New submission | | OWN | |
| Signature Leavy Rah | | | Name and Title Craig Parks Vice President, Research & Development | | Date Decembe 20, 2011 |

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| | | DATA MATRIX | | | |
|---|----------------------|-------------|---|--------|------------------------------|
| Date December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | |
| pplicant's/Registrant's Nanic & Address Tirbac AH, Inc O Box 162059 | | | Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS | | |
| Fort Worth TX 76161 | | | | | <u> </u> |
| Ingredient: Fipronil, Pynproxyfen | | | | | · |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 810.3300 | Efficacy | 44942011 | Merial | PAY | |
| 810.3300 | Efficacy | 44942106 | Merial | PAY | |
| 810.3300 | Efficacy | 45612701 | Merial | PAY | |
| 810.3300 | Efficacy | 45618501 | Merial | PAY | |
| 810.3300 | Efficacy | 45620501 | Merial | PAY | 1 |
| 810.3300 | Efficacy | 45620502 | Merial | PAY | |
| 810,3300 | Efficacy | 45620503 | Merial | PAY | |
| 810.3300 | Efficacy | 45620504 | Merial | PAY | |
| 810.3300 | Efficacy | 45620505 | Merial | PAY | |
| 810.3300 | Efficacy | 45620506 | Merial | PAY | |
| 810.3300 | Efficacy | 45628101 | Merial | PAY | - |
| 810.3300 | Efficacy | 45628102 | Merial | PAY | |
| 810.3300 | Efficacy | 45628103 | Merial | PAY | |
| 810.3300 | Efficacy | 45628104 | Merial | PAY | |
| 810.3300 | Efficacy | 45628105 | Merial | PAY | |
| 810,3300 | Efficacy | 45628201 | Merial | PAY | 1 |
| 810.3300 | Efficacy | 45866901 | Merial | PAY | |
| 810.3300 | Efficacy | 45866902 | Merial | PAY | |
| 810.3300 | Efficacy | 46019201 | Merial | PAY | |
| 810.3300 | Efficacy | 46019202 | Merial | PAY | |
| Signature Leavy Kach | | | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 |

A

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| | DATA | A MATRIX | | | |
|--|---|-------------|---|--------|------------------------------|
| Date: December 20 | , 2011 | | EPA Reg. No./File Symbol 2382-TBA | | Page 6 of 9 |
| Applicant's/Registra Virbae AH, hie | nt's Nanc & Address | | Product: | | |
| PO Box 162059 Fon Worth TX 76161 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | | |
| Ingredient: Fipronil, | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Child Resistant F | ackaging | | | | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator lube test for Child-Resistant Effectiveness | 48095221 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Child-Resistant Effectiveness | 48095222 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Child-Resistant Effectiveness | 48095223 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48095224 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators lube test for Senior-Use Effectiveness | 48095225 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Senior-Use Effectiveness | 48095226 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68ml water, 1 applicator tube test for Child-Resistant Effectiveness | 48095227 | Virbae All, Inc. | OWN | |
| Signature Leavy to | | | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 |

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| 5, 2011 | | EPA Reg. No./File Symbol 2382-TBA | | |
| ant's Name & Address | · | Product: | | |
| | | | | |
| | | EFFIPRO® PLUS TOPICAL SOLUT | TON FOR DOGS | |
| | | | | <u> </u> |
| | | | | |
| Guideline Study Name | MRID Number | Submitter | Statux | Note |
| | 10007000 | | | Į <u></u> |
| Evaluation of the 3 inl Applicator Tube with 2.68 inl water, 6 applicators tube test for Child-Resistant Effectiveness | 48095228 | Virbac All, Inc. | OWN | |
| Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Child-Resistant Effectiveness | 48095229 | Virbac AH, Inc. | OWN | |
| Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48095230 | Virbac AH, Inc. | OWN | |
| Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 | 48095231 | Virbac AH, Inc. | OWN | |
| Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Senior-Use Effectiveness | 48095232 | Virbac AH, Inc. | OWN | |
| Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 1 applicator tube test for Child-Resistant Effectiveness | 48095233 | Virbac AH, Inc. | OWN | |
| Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness | 48095234 | Virbac AH, Inc. | OWN | |
| Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 | 48095235 | Virbac Al-l, Inc. | OWN | |
| | ·····• | Name and Title | | Date |
| | | Craig Parks Vice President, Research & Develop | ment | December 20, 2011 |
| | 2011 ant's Name & Address 61 Pyriproxyfen Guideline Study Name Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Child-Resistant Effectiveness Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicalors tube test for Child-Resistant Effectiveness Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Senior-Use Effectiveness Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Senior-Use Effectiveness Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 1 applicator tube test for Child-Resistant Effectiveness Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 applicators tube test for Child-Resistant Effectiveness | Pyriproxyfen Guideline Study Name Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Child-Resistant Effectiveness Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Cluid-Resistant Effectiveness Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicator tube test for Cluid-Resistant Effectiveness Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Senior-Use Effectiveness Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Senior-Use Effectiveness Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 1 applicator tube test for Child-Resistant Effectiveness Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 applicators tube test for Child-Resistant Effectiveness Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 applicators tube test for Child-Resistant Effectiveness | EPA Reg. No./File Symbol 2382-TB | EPA Reg. No./File Symbol 2382-TBA |

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| | DAT | A MATRIX | | | *************************************** |
|------------------------------------|--|-------------|---|--------|---|
| Date: December 20, | | <u> </u> | EPA Reg. No./File Symbol 2382-TBA | | |
| | nt's Name & Address | | Product: | | |
| Virbae Atl, Inc | | | | | |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | R DOGS | |
| Fort Worth TX 7616 | | | | | |
| tngredient: Fipronil, Guideline | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Reference Number | | | | | Note |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Child-Resistant Effectiveness | 48410001 | Virbae AH, Inc. | OWN | _ |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48410002 | Virbae All, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Child-Resistant Effectiveness | 48410003 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Senior-Use Effectiveness | 48410004 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the line applicator tube with 0.67 ml water, 36 applicator tube test for Child-Resistant Effectiveness | 48410005 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Senior-Use Effectiveness | 48410006 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the Iml applicator tube with 0.67 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410007 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Senior-Use Effectiveness | 48410008 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410009 | Virbac AH, luc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 1,34 ml water, 3 applicator tube test for Senior-Use Effectiveness | 48410010 | Virbae AFI, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410011 | Virbac AH, Inc. | OWN | |
| Signature Lang Kah | | | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 |

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| | DAT | A MATRIX | • | | |
|---|--|-----------------|--|--------|-----------------------|
| Date December 20, 2 | | ZA ZIAZIA INGZA | EPA Reg. No./File Symbol 2382-TBA | | Page 9 of 9 |
| Applicant's/Registrant's Name & Address | | | Product: | | |
| Virbae AH, Inc | | | | | |
| PO Box 162059 | | | EFFtPRO® PLUS TOPICAL SOLUTION FO | | |
| Fort Worth TX 7616 | | | | | |
| Ingredient: Fipronil, | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Ninnber | Submitter | Status | Note |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2,68 ml water, 3 applicator tube test for Schior-Use Effectiveness | 48410012 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410013 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Senior-Use Effectiveness | 48410014 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2,68 ml water, I applicator tube test for Senior-Use Effectiveness | 48410015 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 36 applicator tube test for Senior-Use Effectiveness | 48410016 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6ml applicator tube with 4.02 ml water, 6 applicator tube test for Semior-Use Effectiveness | 48410017 | Virbac AH, Inc. | OWN | |
| Signature | · · · · · · · · · · · · · · · · · · · | | Name and Title | | Date |
| Craig take | | | Craig Parks Vice President, Research & Development | | December 20, 201 t |

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| | DA | TA MATRIX | | | |
|--|--|---------------------------------|---|-------------|----------------------------|
| Date: August 23, 2011 | | EPA Reg No./File Symbol 87825-R | | Page 1 of 6 | |
| Applicant's/Registrant's Name & Address | | | Product: Fipronil Teclmical | | <u> </u> |
| Virbac SA | | | | | 1 |
| Tere avenue 2065 M - LID | | | | | |
| F-06516 Carros, France Ingredient: Pipronil | | | · · · · · · · · · · · · · · · · · · · | | 1 |
| Guideline Reference Number | Guideline Study Name | MRID Number | Sulmitter | Status | Noie |
| Product Chemistry Test Guid | | | | 1 | 110.5 |
| 830.1550 | Product Identity and Composition | 48095240, 48449201 | Virbac. | OWN | |
| 830.1600 | Description of Materials Used | 48095240 | Virbac | OWN | <u> </u> |
| 830.1620 | Description of Production Process | 48095239 | Virbac | OWN | |
| 830.1650 | Description of Formulation Process | 48095239 | Virbac | OWN | |
| 830.1670 | Description of Formation of Impurities | 48095240, 48449201 | Virbac | OWN | |
| 830.1700 | Preliminary Analysis | 48095241 | Virbac | OWN | |
| 830.1750 | Certified Limits | 48095240, 48449201 | Virbac | OWN | |
| 830.1800 | Analytical Method | 48095242 | Virbac | OWN | |
| 830.1900 | Submittal of samples | | Virbac | N/A | |
| 830.6302 | Color | 48095240, 48095243 | Virbac | OWN | |
| 830.6303 | Physical State | 48095240, 48095243 | Virbac | OWN | |
| 830.6304 | Odor | 48095243 | Virbac | OWN | |
| 830.6313 | Accelerated Storage Stability-Metal Ions | 48095243 | Virbac | OWN | |
| 830.6314 | Oxidation/reduction | 48095239 | Virbac | OWN | |
| 830.6315 | Flaminability | 48095239 | Virbac | OWN | |
| 830.6316 | Explodability | 48095239 | Virbac | NR | |
| 830.6317 | l Yr. Storage Stability | | Virbac Name and Title | OWN | See note page 2 |
| Signature | Marie Carlo | | Name and Title Jean-Pascal Marc Corporate Product Innovation Director | | Date August 23, 2011 |

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| DATA MATRIX | | | | | | |
|--|---|-------------|---------------------------------|-----------|----------------------------|--|
| Date August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | | Page 2 of 6 | |
| Applicant's/Registrant's Name & Add Virbac SA 1ere avenue 2065 M - LtD F-06516 Carros, France | ress | | Product: Fipronil Technical | | | |
| Ingredient: Pipronil | | | | | | |
| Guideline Reserence Number | Guideline Study Name | MRID Number | Submitter | Status | Note | |
| 830.6318 | Viscosity | | Virbac | N/A | | |
| 830.6319 | Miscibility | | Vírbac | N/A | Solid | |
| 830.6320 | Corrosion characteristics | | Virbate | OWN | See note page 2 | |
| 830.6321 | Dielectric breakdown voltage | | Virbac | N/A | Watved | |
| 830.7000 | pH | 48095247 | Virbac | OWN | | |
| 830.7200 | Melting Point | 48095249 | Virbac | OWN | | |
| 830.7300 | Density bulk density or specific gravity | 48095250 | Virbae | OWN | | |
| 830.7320 | Particle Size | | Virbac | N/A | | |
| 830.7050 | UV/Visible Spectrum | 48095248 | Virbac | OWN | | |
| 830.7370 | Dissociation constant | 48095251 | Virbac | OWN | | |
| 830.7520;830.7550; 830.7560 830.7570 | Octanol/water partition coefficient | 48095244 | Virbac | OWN | | |
| 830.7840;830.7860 | Solubility | 48095245 | Virbac | OWN | | |
| 830.7950 | Vapor pressure | 48095246 | Virbac | OWN | | |
| Jean-Pascal Marc | | | | | Date August 23, 2011 | |
| | Accions Assilable Submit ands Baner terrior | | Angury Intern | . I II C. | | |

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Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.

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| | D | ATA MATRIX | | | |
|--|---|--------------------------------|---|--|--|
| Date: August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | | Page 3 of 6 |
| Applicant's/Registrant's Name & A Virbac SA Iere avenue 2065 M - LID F-06516 Carros, France | ddress | | Product: Fipronil Technical | | |
| Ingredient: Pipronil | | | | ······································ | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Starus | Note |
| 40 CFR 158.340 Toxicology D | ata Requirements | | | | |
| 870.1100 | Acute oral toxicity | 42918628; 43235401 43279706 | BASF | OLD | |
| 870.1200 | Acute dermal toxicity | 42918629 | BASF | OLD | |
| 870.1200 | Acute dermal toxicity | 43235402 | BASF | OLD | |
| 870.1300 | Acute inhalation toxicity | 42918631 | BASF | OLD | |
| 870.2400 | Primary eye irritation | 42918632 | BASF | OLD | |
| 870.2500 | Primary dermal irritation | 42918630 | BASF | OLD | |
| 870.2600 | Dermal sensitization | 42918634 | BASF | OLD | |
| 870.6100 | Acute delayed neurotoxicity | 42918635 | BASF | OLD | |
| 870.6100 | Acute delayed neurotoxicity | 43559501 | BASF | OLD | |
| 870.3100 | 90-day oral toxicity - rodent | 42918643 | BASF | OLD | |
| 870.3150 | 90-day oral toxicity - nonrodent | 42918642 | BASF | OLD | |
| 870,3200 | 21-day dermal toxicity | 42918644 | BASF | OLD | |
| 870.3250 | 90-day dermal toxicity | DATA GAP | BASF | GAP | *Sec below |
| 870.6100 | 90-day neurotoxicity – mammal | 43291703 | BASF | OLD | |
| 81-8 | Neurotoxicity to Rats by Acute Oral Administration | 44431801 | BASF | PAY | |
| Signature | | | Name and Title Jean-Pascal Marc Corporate Product Innovation Director | | Date August 23, 2011 |

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| Date August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | | Page 4 of 6 |
|---|---|--|---|------------|----------------------------|
| Applicant's/Registrant's Name & Address Virbae SA Icre avenue 2065 M - LID F-06516 Carros, France | | | Product: Fipronil Technical | | |
| Ingredient: Fipronil | | | | | |
| Guideline Reference Number | Guideline Stody Name | MRID Number | Submitter | Status | Note |
| 40 CFR 158.340 Toxicology D | Pata Requirements (Continued) | | | | |
| 84-2 | Structural chromosomal aberration | 42918680 | BASF | OLD | |
| 84-2 | Structural chromosomal aberration | 42918653 | BASF | OLD | |
| 84-2 | Other genotoxic effects | 42918651;42918653 43501703 | BASF | OLD | |
| 85-1/870,7485 | General metabolism | 42918655 | BASF | OLD | |
| 85-1/870,7485 | General metabolism | 43253701 | BASF | PAY | |
| 85-1/870.7485 | General metabolism | 43737308 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42918654 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42977904 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 43253701 | BASF | OLD | |
| 85-2/870.7600 | Dennal penetration | 43737308 | BASF | PAY | |
| 85-7/870.7600 | Immunotoxicity | DATA GAP | | GAP | *See below |
| 40 CFR 158.490 Wildlife and | Aquatic Organisms Data Requirements | | | OLD | |
| 71-1/850.2100 | Avian oral LD 50 - mallard or bobwhite | 42918617 42918616 | BASF | OLD | |
| 72-1/850.1075 | Freshwater fish LC 50 – rainbow or bluegill | 42918624;42918673; 42918674;42977902 43279703;43291718 | BASF | OLD OLD | |
| Signature | | | Name and Title Jean-Pescal Mare Corporate Product Innovation Director | | Date August 23, 2011 |

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. WASHINGTON, D.C. 20460

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| | | DATA MATRIX | | | |
|---|-----------------------------|-------------|---|--------|----------------------------|
| Date: August 23, 2011 | | | EPA Reg. No./File Symbol 87825-R | | Page 5 of 6 |
| Virbac SA Tere avenue 2065 M - LID F-06516 Carros, France | | | Product: Fiprouil Technical | | |
| Ingredient: Fipronil | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 83-1/870.4100 | Chronic feeding – rodent | 42918648 | BASF | OLD | |
| 83-1/870,4100 | Chronic feeding - nonrodent | 42918645 | BASF | OLD | |
| 83-1/870.4100 | Chronic feeding - nonrodent | 43402802 | BASF | PAY | |
| 83-2/870.4200 | Oncogenicity - mouse | 42918649 | BASF | OLD | |
| 83-2/870.4200 | Oncogenicity - mouse | 43501702 | BASF | PAY | |
| 83-2/870.4200 | Oncogenicity - rat | 42918648 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rabbil | 42918646 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rat | 42977903 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rat | 44275001 | BASF | PAY | |
| 83-6/870.6300 | Developmental neurotoxicity | 44039002 | BASF | PAY | |
| 83-4/870.3800 | Reproduction | 42918647 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 42918652 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 42918679 | BASF | OLD | |
| 84-2/870,5100 | Gene mutation | 43291716 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291717 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291721 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291722 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43401102 | BASF | OLD | [|
| Signature : | i com | | Name and Title Jean-Pascal Marc Corporate Product Innovation Direct | ctor | Date August 23, 2011 |

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| | DA | TA MATRIX | | | |
|---|---|-------------|--|----------|--------------------|
| Date: August 23, 2011 | | ···· | El'A Reg. No./File Symbol 87825-R | | |
| Applicant's/Registrant's Name & Addr Virbae SA Iere avenue 2065 M - LID F-06516 Carros, France | ess | | Product: Fipronil Technical | | Page 6 of 6 |
| Ingredient; Fipronil | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 72-2/850.1010 | Acute LC 50 freshwater invertebrates (Daphnia magna) | 42918625 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daphnia magna) | 42918669 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daphnia magna) | 42918671 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daphnia magna) | 43291719 | BASF | OLD | |
| 835.2110 | Hydrolysis | 42977905 | BASF | OLD | |
| 40 CFR 158.390 Reentry Protection Data Requirements | | | | | |
| 133-3 | Dermal exposure - Fiprouil | 44433302 | Merial | PAY | |
| 133-4 | Inhalation exposure - Fipronil | 44433302 | Merial | PAY | |
| 132-1 | Dislodgeable residue dissipation - Fipronil | 44531203 | Merial | PAY | |
| N/A | Dermal and inhalation exposure of commercial pet groomers (Spot) - Fiprouil | 44433303 | Merial | PAY | |
| N/A | Analytical method for exposure studies - Fipronil | 44433308 | Merial | PAY | |
| <i></i> | 1) | | Name and Title Jean-Pascal Mare Corporate Product Innovation I | Director | August 23, 2011 |

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^{*} Pursuant to 40 CFR 152.96 (c), Virbac hereby certifies that Virbac has no basis to believe that this requirement is not a data gap and, further, that Virbac has sent by certified until to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbac will update the Agency as to the information, if any, Virbac receives in response to this "data gap" letter.

| Receipt for Section 3 | | | |
|---------------------------------------|-------------------------------------|---|--|
| S 916101 | Resubmission: C | Ves C No | Print Letter |
| Regulatory Type: Product Registration | | | Enter More Information |
| Application Type: Pending Product An | | Yes (No | Tracking |
| Company: 2595 THE HART | Z MOUNTAIN CORPORATION V | | |
| Risk Manager: Registration Division | , Risk Management Team 10 | | |
| Product # 2596-RAG Pro | duct Name; HARTZ REFERENCE #128 | | |
| Overnde# | | | |
| Me Too Section3: | Me Too Product Name | | |
| Application Date: 27-Apr-2012 | OPP Rec'vd Date: 01-May-2012 | Recept Co | riteri Des |
| Front End Date: 01-May-2012 | Risk Manager Send Date: 02-May-2012 | Paper Label | |
| FFS Due Date; OPP Target Date; | Negotiated Due Date: | | |
| Fast Trace: | New Ingredient: | J <u></u> <u>₹</u> <u>1</u> <u>1 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 </u> | View/Edit |
| Receipt Description: Label Amendment | | New Ingredient | The second secon |
| | | Feducat Cate | |
| | | New Ingredient Received Date | |
| Form A. 🔲 Signature Del | Form 8 | Signature Date: | |
| | | | HARVEY STATES |

Resubmission

Fee for Service

{916101b~

| This package includes the following | for Division |
|---|---------------------------------|
| New Registration | ○ AD |
| Amendment | ○BPPD ○RD |
| □ Studies? □ Fee Waiver? □ volpay % Reduction: | Risk Mgr. 10 |
| Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date: | 916101 2596-RAG 4/30/2012 |
| This item is NOT subject to | FFS action. |
| Action Code: Requested: Granted: Amount Due: \$ | Parent/Child Decisions: |
| ■ Inert Cleared for Intended Use | Uncleared Inert in Product |
| Reviewer: Phul Dani Olive | Date: <u>5/2/12</u> |
| Remarks: Resulpinission | |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

May 2, 2012

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

LANCE HEMSARTH THE HARTZ MOUNTAIN CORPORATION 400 PLAZA DRIVE SECAUCUS, NJ 07094-

PRODUCT NAME: HARTZ REFERENCE #129

COMPANY NAME: THE HARTZ MOUNTAIN CORPORATION

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 2596-RAU EPA RECEIPT DATE: 05/01/12

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

April 27, 2012

Document Processing Desk Office of Pesticide Programs (7504P) US Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Attention:

Mr. Richard Gebken (PM # 10)

RE:

HARTZ REF #128, EPA Reg. No. 2596-RAG HARTZ REF #129, EPA Reg. No. 2596-RAU HARTZ REF #130, EPA Reg. No. 2596-RAL HARTZ REF #131, EPA Reg. No. 2596-RAA

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing modified labels based on the feedback from Rosalind Gross and her review of the CRP data for the above listed registrations. Changes were made only to the directions for use sections in order to match the instructions for use in the child resistant packaging testing labels.

These master labels replace the current labels that were submitted for the above listed registrations. Please find enclosed 3 copies of each Master Label.

If you have any questions or need any additional information, please feel free to call me at (201) 271-4800, ext. 7302 or smcnear@hartz.com.

Sincerely,

Sean McNear

Director Regulatory Affairs

Enclosures

| Ploase read instructions | on reverse before comple | ting form. | | Form Ap | proved, | OMB No. 207 | 0-0080 | Print Form |
|--|--|---|--|---|------------------------|------------------------------|--|--|
| \$EPA | Environmenta | Inited States I Protecti ngton, DC 20 | _ | псу | × | Registrat Amendm Other | | OPP Identifier Number |
| | | Applicati | on for P | esticide - Se | ction | 1 | | |
| 1. Company/Product Nu 2596-RAG | mber | | | 2. EPA Product M Richard Gebken | | | 3. Pro | pposed Classification |
| 4. Company/Product (Na Hartz Ref. 128 | sma) | | | PM# 10 | | | <u> </u> | None Restricted |
| 5. Name and Address of The Hartz Mountain 400 Plaza Drive, Seca | • | de(| | (b((i), my produc to: | t is sim | ilar or identic | al in col | FIFRA Section 3(c)(3) mposition and labeling |
| Check if | this is a new address | | | Product Name | <u> </u> | | | ······································ |
| | | | Secti | on - Il | | | | |
| Amendment - Ex | rasponsa to Agency letter | deted | · •••••••••••••••••••••••••••••••••••• | Final print Agency in "Mo Too" Other - Es | itter dati 'Applica | tion. | | |
| | on the fee d back from Ro the child resistant pack | | test. | made to the ma | ster labe | el directions f | or use to | o be exactly the same |
| 1. Material This Product | Will Be Packaged in: | | <u> </u> | | ····· | | | |
| Child-Resistant Packagin X Yes* No * Certification must be submitted | Yes No | No. per conteiner | | oluble Packeging fes lo No. per wgt contain | | | onteiner Metal Plactic Glase Paper Other [S | pocify) |
| 3. Location of Nat Conta | nte Information | 4, Size(s) Re | L Contains | | 15 100 | ation of Label | Direction | ne |
| Label | Conteiner | 4. Sizeta) No | can containe | | | On Label | | panying product |
| 6. Manner in Which Labo | of is Affixed to Product | Lithor Paper Stend | ileq Glood Staby | Oth | | | | |
| | | | | n - IV | | · · · · | | |
| 1. Contact Point (Comp. | lere irems directly bolow fo | or Idensificasi | on of individ | uel to be contacted | i, il nece | ssary, lo proc | ess (his . | applicution,) |
| Name Sean McNear | | | Title Director R | eg. Affairs | | 1 | elephone 01-271- | No. (Include Area Code) |
| | tefomente i havo msde on t sny knowingly false or m bie law. | | all attachm | | | | | 8. Oate Application Ruceived (Stamped) |
| 2. Signatura | Mille | | 3. Title Director R | egulatory Affairs | | | | 1111 |
| 4. Typed Name | , | | 5. Date | | | | | 5. 3. 3 5. |

April 27, 2012

Sean McNear

DATA EVALUATION RECORD

PYRIPROXYFEN AND FIPRONIL [104.11; EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS]

STUDY TYPE: ACUTE ORAL TOXICITY - RAT [OCSPP 870.1100; OECD 425] ACUTE DERMAL TOXICITY - RAT [OCSPP 870.1200; OECD 402] ACUTE EYE IRRITATION - RABBIT [OCSPP 870.2400; OECD 405] ACUTE DERMAL IRRITATION - RABBIT [OCSPP 870.2500; OECD 404] DERMAL SENSITIZATION - GUINEA PIG [OCSPP 870.2600; OECD 406] MRID: 486969-10, 486969-11, 486969-12, 486969-13, and 486969-14

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by Summitec Corporation 9724 Kingston Pike, Suite 602 Knoxville, Tennessee 37922

Task Order No. 3-C-10

| DAMARA I EAGA |
|--|
| Signature: 1 ON LA L. F. C. R. Date: APR 16 2012 |
| |
| Thomas C. Marchall |
| Signature: INUNION CITIES |
| Date:APR 1 6 2012 |
| Rale W Rasa |
| Signature: |
| Date: App 1 & 2012 |
| 1 |
| Signature: HNOUA. 11. Edmord |
| Date: APR 1 6 2012 |
| |

Disclaimer '

This review may have been altered subsequent to the contractor's signatures above.

chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]*

*[Protective eyewear may be specified, if appropriate].

First Aid:

If on skin:

- -Take off contaminated clothing.
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

If swallowed:

- -Call a poison control center or doctor immediately for treatment advice.
- -Have person sip a glass of water if able to swallow.
- -Do not induce vomiting unless told to by a poison control center or doctor.
- -Do not give anything to an unconscious person.

If in eyes:

- -Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- -Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- -Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

5. The basic CSF dated October 21, 2011 for 2382-RIO should be reviewed and accepted by the TRB Chemistry Team.

BACKGROUND:

The material received for review includes a proposed label, indicating the product is packaged in single-use applicators (1, 3, 6 or 36 applicators per package). Dosage rates are stated to be 0.023 fl. oz. (0.67 mL) "for small dogs and puppies 8 weeks old or older and up to 22.9 lbs," 0.045 fl. oz. (1.34 mL) for dogs weighing 23-44.9 lbs, 0.091 fl. oz. (2.68 mL) for dogs weighing 45-88.9 lbs, and 0.136 fl. oz. (4.02 mL) for dogs weighing 89-132 lbs. The product is to be applied no more frequently than once a month ("Effective monthly control of fleas and ticks," and "Once monthly application." There are five acute toxicity studies (MRID 48696910, acute oral toxicity study in rats; 48696911, acute dermal toxicity study in rats; 48696912, acute eye irritation study in rabbits; 48696913, acute dermal irritation study in rabbits; and 48696914, contact hypersensitivity in albino guinea pigs, Buehler test), and a waiver request for the inhalation toxicity study requirement. In addition, there is a basic CSF, dated October 21, 2011.

COMMENTS AND RECOMMENDATIONS:

- 1. The acute toxicity studies in MRIDs 48696910-48696914 were reviewed by a contractor, Summetic. The resulting DER was reviewed by TRB, and the appropriate revisions, if necessary, were made. It is concluded that these five acute toxicity studies are acceptable, and can be used to support the registration of 2382-RIO.
- 2. TRB has reviewed the acute inhalation toxicity study waiver request, and concludes that, based on the proposed product use and minimal potential inhalation exposure, this study can be waived and the product can be assigned to Toxicity Category IV by the inhalation exposure route.
- 3. Based on the results of the acute toxicity studies, the following is the acute toxicity profile for 2382-RIO (EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS):

| Acute oral toxicity | 111 | Acceptable | MRID 48696910 |
|---------------------------|----------|------------|---------------|
| Acute dermal toxicity | III | Acceptable | MRID 48696911 |
| Acute inhalation toxicity | ΙV | Waived | n/a |
| Primary eye irritation | III | Acceptable | MRID 48696912 |
| Primary dermal irritation | IV | Acceptable | MRID 48696913 |
| Dermal sensitization | Negative | Acceptable | MRID 48696914 |

4. Based on the acute toxicity profile above, the following is the precautionary and first aid labeling for 2382-RIO, as obtained from the TRB Label Review System.

PRODUCT ID #:

002382-00189

PRODUCT NAME:

EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS

PRECAUTIONARY STATEMENTS

SIGNAL WORD:

CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking,



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

May 15, 2012

MEMORANDUM

Subject:

Name of Pesticide Product: EFF1PRO® PLUS TOPICAL SOLUTION FOR DOGS

EPA Reg. No. /File Symbol: 2382-RIO

DP Barcode:

DP 398341 459013

Decision No.: Action Code:

R310

PC Codes:

129032 (Pyriproxyfen: 2.9%)

129121 (Fipronil: 9.7%)

From:

Byron T. Backus, Ph.D., Toxicologist Byron T. Ba

To:

Bonaventure Akinlosotu/Richard Gebken RM 10

Insecticide Branch

Registration Division (7505P)

Registrant:

VIRBAC AH, INC.

FORMULATION FROM LABEL:

| Active Ingredient(s): | | <u>by wt.</u> |
|-----------------------|-------|---------------|
| 129121 Fipronil | | 9.7% |
| 129032 Pyriproxyfen | | 2.9% |
| Other Ingredient(s): | | <u>87.4%</u> |
| • | TOTAL | 100.0% |

ACTION REQUESTED: The Risk Manager requests:

"For your review: R310. MRID 486969-10 to -14; for a Fipronil + Pyriproxyfen containing Spot-On for dogs. Submits prod chem., tox, efficacy and CAS data..."

| A CONTRACTOR OF THE PROPERTY O | | T | | |
|--|--|---|------|----------|
| Acute dermal toxicity / rat | 48696911 | $LD_{50} > 2000 \text{ mg/kg (both sexes)}$ | I11 | A |
| Harlan Laboratories Ltd. | | No deaths, abnormal systemic | | |
| (Itingen, Switzerland) | | clinical signs, or abnormal gross | | |
| Study #D34677 / November 18, | | findings; BW affected: 4/5 males | | \ |
| 2011 | | and 4/5 females lost weight during | | <u> </u> |
| OCSPP 870.1200; OECD 402 | | days 1-8, all animals gained during | | |
| es de la companya de | | days 8-15 and most had net BW | | |
| SAME AND | | gain over days 1-15 (1 female had | ĺ | |
| | | net loss over days 1-15); local | | |
| 55141 | | effects: erythema on 1 male on day | | |
| | | 2 (resolved by day 3), | | |
| | | desquamation and/or focal crusts | | |
| a. | | on 5/5 males and 4/5 females | | |
| H | | beginning days 2-6 (resolved by | Ì | |
| 1842 1842 1842 1843 1844 1844 1844 1844 1844 1844 1844 | | day 15 except desquamation in 1 | | |
| UNITED THE PROPERTY OF THE PRO | | male and I female). | | |
| | | Note: It is unclear whether the size | | |
| | | of the dose site really was 10% of | | |
| 1 | | the body surface area (BSA). The | | |
| 1911 | | study author stated that application | | |
| | | | | |
| | | sites were approximately 10% of | | |
| delication of the state of the | | body surface area, but it was also | | |
| | | stated that application sites were | | `` |
| | | covered by a gauze pad measuring | | |
| 5544445 | | ~25 cm², which, according to | | |
| THEORYGEN | | standard formulas, would be less | | |
| NO CONTRACTOR OF THE PROPERTY | | than 10% of the BSA for rats in the | | |
| | | BW range used in this study (193.7- | | |
| | | 276.8). | | |
| | | Deficiency: Systemic clinical signs | | |
| | | data from days 2-15 were omitted | | |
| | | from the study report. | -4 | |
| Acute inhalation toxicity / rat | n.a. | Waiver recommended on basis of | (lV) | W |
| | | product use (pet spot-on) and | | |
| | | minimal inhalation exposure. | | |
| Primary eye irritation / rabbit | 48696912 | Use of anesthetic not mentioned. | IlI | Α |
| Harlan Laboratories Ltd. | | No corneal or iridial effects seen in | | |
| (Itingen, Switzerland) | | any eye at any time point. | | |
| Study #D34688 / November 30, | | Conjunctival redness present in 3/3 | | |
| 2011 | | eyes at 1 hr through 7 days and in | | |
| OCSPP 870.2400; OECD 405 | | 2/3 and 1/3 eyes at 10 and 14 days | | |
| | | post instillation (score=1-2). | | |
| | | Conjunctival discharge seen in 2 | | |
| **Company | | eyes at 1 hour (score=1) and not | | |
| | | seen thereafter. Slight to moderate | | |
| | | scleral reddening seen in 3 eyes at | | |
| | | 1 hour and in 2 eyes at 24-72 hours. | | |
| | | Conjunctivitis scored as "positive" | | |
| | | in 2/3 eyes at 24-48 hrs and in 1/3 | | |
| | MINANTA MINANT | in 2/3 eyes at 24-48 hrs and in 1/3 | | <u> </u> |

EPA Reviewer: Byron T. Backus, Ph.D.

Risk Manager (EPA): 10

The following table is the Acute Toxicity Data Evaluation Record (DER) for the five studies submitted for the proposed product, File Symbol 2382-RIO

Date: May 15, 2012

| 2. PC CODES: 129032 and 129 | | | | |
|------------------------------|----------|--|-----|-------|
| 3. CURRENT DATE: May 15 | | 4 11100 1 0 C00/ E' 11 10 000/ | | |
| | | A 11123-1; 9.68% Fipronil and 2.98% | | |
| | | liquid (or colorless to yellowish liquid | | |
| | | date: November 2011; stored at room | T | 7 |
| Study/Species/Lab | MRID | Results | Tox | Core |
| Study # /Date | | | Cat | Grade |
| Acute oral toxicity / rat | 48696910 | LD_{50} Females = 2000 mg/kg bw | 11I | A |
| Harlan Laboratories Ltd. | | [95% PL Confidence interval is 0 | | |
| (Itingen, Switzerland) | | to >20,000] | | |
| Study #D34666 / November 18, | | Four tested (with dosing on day 1) | | |
| 2011 | | in accordance with AOT425 | | |
| OCSPP 870.1100; OECD 425 | | StatPgm (assumed sigma=0.5): 1 at | | |
| | | 550 mg/kg, 3 at 2000 mg/kg. | | |
| | | 550 mg/kg: no deaths, abnormal | | ļ |
| | | clinical signs, bw effects, or gross | | |
| | | findings. | | |
| | | 2000 mg/kg: 2 deaths (days 6 & 9); | | |
| | | clinical signs: ruffled fur and/or | | |
| | | hunched posture in 2/3 (day 1); | | |
| | | survivor lost wt days 1-8 but had | | |
| | | net gain for the study overall; gross | | |
| | | necropsy findings limited to lung | | |
| | | congestion in both decedents. | | |
| | | Deviation from OECD 425: no | | 1 |
| | | rationale provided for use of | i | |
| | | starting dose different from default. | | |

| | | eyes at 72 hours. | | |
|--|----------|--------------------------------------|----------|--|
| | | MMTS=3.33, at 1-48 hours; | | |
| GALANA | | Mildly irritating (per Kay and | | |
| P& Monthless | İ | Calandra). | | |
| | | Classified based on resolution of | | |
| | | | | |
| | | "positive" irritation within 7 days | | |
| The state of the s | 40000013 | or less. | 13.7 | |
| Primary dermal irritation / | 48696913 | PDI at 72 hours=0.00 | IV | A |
| rabbit | | There were no observations of | | |
| Harlan Laboratories Ltd. | | erythema, edema, or other changes | | |
| (Itingen, Switzerland) | | to the skin on any animal at any | | |
| Study #D34690 / November 30, | | time point. | | |
| 2011 | | "Nonirritant" based on US EPA | | İ |
| OCSPP 870.2500; OECD 404 | | (1988). | | |
| Dermal sensitization / guinea | 48696914 | Tested using Buehler method | | A |
| pig | | Induction used 100% | | |
| Harlan Laboratories Ltd. | | concentration; challenge used 75% | | |
| (Fullinsdorf, Switzerland) | | concentration in diethylene glycol | | |
| Study #D34701 / October 27, | | monoethyl ether vehicle. | | |
| 2011 | | No positive dermal reactions on | |] |
| OCSPP 870.2600; OECD 406 | | treated or vehicle control animals | ! | *************************************** |
| D03434444 | | following challenge. | | 5000 |
| M-945 | | Not a sensitizer | | MANUAL MA |
| | | Deficiencies: Justification not | | NA SASSA |
| *************************************** | | provided for usage of non-standard | | i swa |
| NA PARAMETER AND AND AND AND AND AND AND AND AND AND | | vehicle. It appears that in the | | |
| OCCUPATION AND ADMINISTRATION AN | | positive control study the testing | | |
| SCHALL PROPERTY OF THE PROPERT | | lab was not able to identify the | | |
| | | HNIC; two challenge | | 4 |
| 774 | | concentrations (neither of which | | |
| | | was a HNIC) were selected, based, | | |
| | | in part, upon historical results. | | 300,000,000 |
| | | Results of initial challenge were | | # 54 H |
| шкальны | | equivocal, and a re-challenge was | | |
| | | necessary. "Correct" results were | | |
| | | attained, but the laboratory has not | | e de la companya de l |
| | | necessarily demonstrated | | |
| | | proficiency. | | |
| | | J | <u> </u> | |

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap, W = Waived

DATA PACKAGE BEAN SHEET

Date: 02-Feb-2012

Page 1 of 2

Decision #: 459013

DP #: (398344)

PRIA

Parent DP #:

Submission #: 908748

E-Sub #: * * * Registration Information * * * Registration: 2382-RIO - EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS Company: 2382 - VIRBAC AH, INC. Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237 Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS Sent Date: Calculated Due Date: 10-Jul-2012 Edited Due Date: Type of Registration: Product Registration - Section 3 Action Desc: (R310) NEW PRODUCT; NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST Ingredients: 129032, Pyriproxyfen(2.9%) 129121, Fipronil(9.7%) * * * Data Package Information * * * Expedite: () Yes No Due Back: Date Sent: 02-Feb-2012 DP Ingredient: 129121, Fipronil 129032, Pyriproxyfen DP Title: tox/cas Parent DP #: CSF Included: Yes No Label Included: 🙆 Yes 🔘 No Date In Assigned To Date Out Last Possible Science Due Date: 10-Jun-2012 Organization: RD / TRB Team Name: TOX Science Due Date: Reviewer Name: Backus, Byron Sub Data Package Due Date:

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

For your review: R310

Contractor Name:

MRID 48696916; for a Fipronil + Pyriproxyfen containing Spot-On for dogs.

Submits prodichem, tox, efficacy and CAS data; Cites CRP data.

Thanks, B.A.

Surmort

Page 2

* * * Studies Sent for Review * * * Decision#: (459013) DP#: (398344) MMILL MRIO Status Citation Reference Guideline Rich Status 870.7200/Companion animal 48696916

Villard, I. (2011) Summary of Companion
Animal Safety Data for Effipro Plus Topical
Solution for Dogs (Fipronil 9.7% and
Pyriproxyfen 2.9% End Use Product). Project
Number: VIRBAC/104/11/1. Unpublished study
prepared by Isa Vet Biosciences 51p.

Pass (10-Jan-2012)

DATA PACKAGE BEAN SHEET

Date: 02-Feb-2012 Page 1 of 2

Decision #: 459013

DP #: (398341)

PRIA

Parent DP #:

Submission #: 908748

| e de la companya de la companya de la companya de la companya de la companya de la companya de la companya de La companya de la et anna et net et et et e | * * * Registration I | nformation * | * * | E-Sub #: |
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| | | IPRO PLUS TOPICAL | •///// | R DOGS | - (2011) of |
| Company: | 2382 - VIRBAC AH, | INC. | | | - (7310 vot |
| Risk Manager: | RM t0 - Richard Ge | bken - (703) 305-6701 Room | # PY1 S-7237 | | 15 |
| Risk Manager Reviewer: | Bonaventure Akinlo | sotu BAKINLOS | | | 1/ |
| Sent Date: | | Calculated Due | Date: 10-Jul-2012 | Edite | ed Due Date: |
| Type of Registration: | Product Registration | - Section 3 | | | |
| Action Desc: | (R310) NEW PROD | UCT;NON-FAST TRACK (IN | CLUDES REVIEWS | OF PRODUCT CHEM | DST . |
| Ingredients: | t 29032, Pyriproxyfe | n(2.9%) | | | |
| | 129121, Flpronil(9.7 | %) | | | |
| | * | * * Data Package | Information * | ** | |
| Expedite: | O Yes No | Oate | Sent: 02-Feb-2012 | | Due Back: |
| DP Ingredient: | 129032, Pyriproxyfe | n | | | ······ |
| | 129121, Fipronil | | | | ************ |
| DP Title: | tox/pl | | | | |
| CSF Included: | Yes No | Label Included: 🌘 Ye | s 🔾 No 💮 Pare | ent DP #; | |
| Assigned To | 0 | Date In | Date Out | | |
| Organization: RD / T | RB | | | Last Possible Science | ce Due Date: 10-Jun-2012 |
| Team Name: TOX | | | | Scienc | ce Due Date: |
| Reviewer Name: Backu | s, Byron | | | Sub Data Packag | ge Due Date: |
| Contractor Name: 5 | ummoli | | | | |

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

For your review: R310

MRID 486969 - t0 to -t4; for a Fipronil + Pyriproxyfen containing Spot-On for dogs.

Submits prod chem, tox, efficacy and CAS data; Cites CRP data.

Thanks, B.A.

48696914

| rage 2 | 1 | |
|---|---|---|
| * * * Studies Sent for Review * * | ** | Decision#: (459013) |
| is Chation Reference | Gudeline | 59-5 9fatus |
| Damme, B. (2011) 104.1 t: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure; Final Report. Project Number: D34666, Unpublished study prepared by Harlan Laboratories, Ltd. 69p. | · | Pass (10-Jan-2012) |
| Damme, B. (2011) 104.11: Acute Dermal Toxicity Study in Rats: Final Report. Project Number: D34677. Unpublished study prepared by Harlan Laboratories, Ltd. 66p. | 870. t200/Acute dermal toxicity | Pass (10-Jan-2012) |
| Damme, B. (2011) 104.11: Acute Eye Irritation Study in Rabbits: Final Report. Project Number: D34688. Unpublished study prepared by Harlan Laboratories, Ltd. 72p. | 870.2400/Acute eye irritation | Pass (10-Jan-2012) |
| Damme, B. (2011) 104.11: Acute Dermal Irritation Study in Rabbits: Final Report. Project Number: D34690. Unpublished study prepared by Harlan Laboratories, Ltd. 55p. | 870.2500/Acute dermal irritation | Pass (10-Jan-2012) |
| Arcelin, G. (2011) 104.11: Contact Hypersensitivity in Albino Pigs, Buehler Test: Final Report, Project Number: D34701. Unpublished study prepared by Harlan Laboratories, Ltd. 101p. | 870.2600/Skin sensitization | Pass (t0-Jan-2012) |
| | *** Studies Sent for Review ** Citation Reference Damme, B. (2011) 104.1 t: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure: Final Report. Project Number: D34666. Unpublished study prepared by Harlan Laboratories, Ltd. 69p. Damme, B. (2011) 104.11: Acute Dermal Toxicity Study in Rats: Final Report. Project Number: D34677. Unpublished study prepared by Harlan Laboratories, Ltd. 66p. Damme, B. (2011) 104.11: Acute Eye Irritation Study in Rabbits: Final Report. Project Number: D34688. Unpublished study prepared by Harlan Laboratories, Ltd. 72p. Damme, B. (2011) 104.11: Acute Dermal Irritation Study in Rabbits: Final Report. Project Number: D34690. Unpublished study prepared by Harlan Laboratories, Ltd. 55p. Arcelin, G. (2011) 104.11: Contact Hypersensitivity in Albino Pigs, Buehler Test: Final Report. Project Number: D34701. Unpublished study prepared by Harlan | *** Studies Sent for Review *** Damme, B. (2011) 104.1t: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure: Final Report. Project Number: D34666. Unpublished study prepared by Harlan Laboratories, Ltd. 69p. Damme, B. (2011) 104.11: Acute Dermal Toxicity Study in Rats: Final Report. Project Number: D34677. Unpublished study prepared by Harlan Laboratories, Ltd. 66p. Damme, B. (2011) 104.11: Acute Eye Irritation Study in Rabbits: Final Report. Project Number: D34688. Unpublished sfudy prepared by Harlan Laboratories, Ltd. 72p. Damme, B. (2011) 104.11: Acute Dermal Irritation Study in Rabbits: Final Report. Project Number: D34690. Unpublished study prepared by Harlan Laboratories, Ltd. 55p. Arcelin, G. (2011) 104.11: Contact Hypersensitivity in Albino Pigs, Buehler Test: Final Report. Project Number: D34701. Unpublished study prepared by Harlan |

DATA PACKAGE BEAN SHEET

Date: 02-Feb-2012 Page 1 of 2

Decision #: 459013

DP#: (398341) ·

PRIA

Parent DP #:

Submission #: 908748

E-Sub #:

* * * Registration Information * * * Registration: 2382-RIO - EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS. Company: 2382 - VIRBAC AH, INC. Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237 Risk Manager Reviewer: Bonaventure Akiniosotu BAKINLOS Calculated Due Date: 10-Jul-2012 Sent Date: Edited Due Date: Type of Registration: Product Registration - Section 3 Action Desc: (R310) NEW PRODUCT; NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIS? Ingredients: 129032, Pyriproxyfen(2.9%) 129 t 21, Fipronil (9.7%) * * * Data Package Information * * * Expedite: Yes No Date Sent: 02-Feb-2012 Due Back: DP Ingredient: 129032, Pyriproxyfen 129121, Fipronil DP Title: tox/pl Label Included: Yes No Parent DP#: CSF included: Yes No Assigned To Date in Date Out Organization: RD / TRB Last Possible Science Due Date: 10-Jun-2012 / Team Name: TOX Science Due Date: Reviewer Name: Backus, Byron Sub Data Package Due Date: Contractor Name: * * * Studies Sent for Review * * * Printed on Page 2 * * * Additional Data Package for this Decision * * *

For your review: R310

MRID 486969 - 10 to -14; for a Fipronil + Pyriproxyfen containing Spot-On for dogs.

Submils prod chem, tox, efficacy and CAS data; Cites CRP data.

Thanks, B.A.

Can be printed on its own page

* * * Data Package Instructions * * *

Waiver Request

Registrant: Virbac Animal Health, Inc. Acute Inhalation Study (OPPTS 830.1300). Effipro Plus Topical Solution for Dogs.

The Effipro® Plus Topical Solution for Dogs product is composed of 9.7% w/w of the active ingredient fipronil and 2.9 % w/w of the active ingredient pyriproxifen. This product is packaged in single use non-refillable applicators that are intended for one time only spot-on applications to dogs.

The potential human inhalation exposure to this product is expected to be neglible. Only very small amounts of product are applied per application, depending the weight of the animal. Based on packaging considerations described in the proposed product labeling, the maximum volume of Effipro® Plus Topical Solution for Dogs that can be administered at one time to a dog using the largest available applicator size is approximately 4.0 ml. This application volume represents the worst case because it is the dose that is recommended only for use on dogs weighing more than 89 pounds. Therefore, according to the proposed label, a great deal of anticipated product use will occur at much lower volumes on smaller dogs.

Furthermore, the measured vapor pressure of both of the active ingredients, fipronil and pyriproxifen, are extremely low (2.8 x 10⁻⁹ mm Hg at 25°C and 1.0 x 10⁻⁷ mm Hg at 25°C, respectively), indicating that both active ingredients are essentially non-volatile and are therefore not expected to vaporize from the skin of the treated animal following application. The active ingredients will therefore not be available for inhalation after application according to label directions. Finally, the method of applying the liquid product directly to the pet creates no particulates, aerosols, or other respirable matter. Therefore, based on the criteria provided by the Agency in 40 CFR 158.500, footnote 4 under the Toxicology Data Requirements, a waiver of the acute inhalation study for these products is appropriate.

DATA PACKAGE BEAN SHEET

Date: 02-Feb-2012 Page 1 of 2

Decision #: 459013 DP #: (398340)

PRIA

Parent DP #:

Submission #: 908748

E-Sub #:

* * * Registration Information * * *

| | | * * * Registration In | formation * | **** | E-3ub #. |
|------------------------|-----------------------|-----------------------------|--|-----------------------|-----------------------|
| Registration: | 2382-RIO - EFF | PRO PLUS TOPICAL S | OLUTION FOR | R DOGS | R3000 |
| Company: | 2382 - VIRBAC AH, | | tet ded med _{seg} arat producende demokratier | J | (> 300 |
| Risk Manager: | RM 10 - Richard Gel | oken - (703) 305-6701 Room# | PYt S-7237 | | |
| Risk Manager Reviewer: | Bonaventure Akinlos | otu BAKINLOS | gagan and an and an and an an an an an an an an an an an an an | | |
| Sent Date: | | Calculated Due D | ate: 10-Jul-2012 | Edited | d Due Date: |
| Type of Registration: | Product Registration | - Section 3 | | | |
| Action Desc: | (R310) NEW PRODI | JCT;NON-FAST TRACK (INC | LUĐES REVIEWS | OF PRODUCT CHEMI | 81 |
| Ingredients: | 129032, Pyriproxyfer | n(2.9%) | | | |
| | 129121, Fipronil(9.79 | 0/1 | | | |
| | * | ** Data Package I | | | |
| Expedite: | Yes No | Date S | ent: 02-Feb-2012 | | Due Back: |
| DP Ingredient: | t29032, Pyriproxyfer | 1 | | | |
| | 129121, Fipronil | | | | |
| DP Title: | prod chem | | ,,.,., | ., | |
| CSF Included: | Yes No | Label Included: Yes | ○ No Pare | int DP #: | |
| Assigned To | 0 | Date In | Dat e O ut | | |
| Organization: RD / T | RB | | | Last Possible Science | Due Date: 10-Jun-2012 |
| Team Name: CHEM | i | | | Science | Due Date: |
| | | | *************************************** | Sub Data Package | e Due Date: |
| | | | | - | |
| | * * : | * Studies Sent for F | Review * * * | | |
| | | Printed on Page 2 | | | |
| | * * * Addition | nal Data Package fo | or this Dacie | ion * * * | |

No Additional Data Packages

* * * Data Package Instructions * * *

For your review: R310

MRID 486969 - 01 to -09; for a Fipronil + Pyriproxyfen containing Spot-On for dogs.

Submits prod chem, tox, efficacy and CAS data; Cites CRP data.

Thanks, B.A.

Page 2

| DP#: (398340) | " " " Studies Sent for Review " | * * | Decision#: (459013) |
|------------------|--|--|---------------------|
| MRID MRID Status | Citation Reference | Gueeline | |
| 48696908 | Zepperitz, C. (2011) (Effipro Plus Topical Solution for Dogs): Quantification of the Active Ingredients Fipronil and Pyriproxyfen in Five Batches by Validated Methods: Final Report. Project Number: D34802. Unpublished study prepared by Harlan Laboratories Ltd. 56p. | 830.1800/Enforcement analytical method | Pass (10-Jan-2012) |
| 48696909 | Zepperitz, C. (2011) 104,11: Enforcement Analytical Method - Quantification of the Active Ingredients Fipronil and Pyriproxyfen: Final Report. Project Number: D34813. Unpublished study prepared by Harlan Laboratories, Ltd. 38p. | · | Pass (10-Jan-2012) |

** * Studies Sent for Review * * *

| DP#: (398340) | | " " Studies Sent for Review " | | Decision#, (459015) |
|-----------------------|-------------|---|---|---------------------|
| MRID | MRID Status | Citation Reference | Guideline | 86.5 519005 |
| 48696901 | | Villard, I. (2011) Product Specific Chemistry for Effipro Plus Topical Solution for Dogs. Project Number: VIRBAC/104/11/3. | 830.1550/Product Identity and composition | Pass (10-Jan-2012) |
| 48696901 | | Unpublished study prepared by Virbac. 40p. Villard, I. (2011) Product Specific Chemistry for Effipro Plus Topical Solution for Dogs. Project Number: VIRBAC/104/11/3. Unpublished study prepared by Virbac. 40p. | 830.1600/Description of materials used to produce the product | Pass (10-Jan-2012) |
| 48696901 | | Villard, I. (2011) Product Specific Chemistry for Effipro Plus Topical Solution for Dogs. Project Number: VIRBAC/104/11/3. Unpublished study prepared by Virbac, 40p. | 830.1620/Description of production process | Pass (10-Jan-2012) |
| 48696901 | | Villard, I. (2011) Product Specific Chemistry for Effipro Plus Topical Solution for Dogs. Project Number: VIRBAC/104/11/3. Unpublished study prepared by Virbac. 40p. | 830,1650/Description of formulation process | Pass (10-Jan-2012) |
| 4869 6 901 | | Villard, I. (2011) Product Specific Chemistry for Effipro Plus Topical Solution for Dogs. Project Number: VIRBAC/104/11/3. Unpublished study prepared by Virbac. 40p. | 830.1670/Discussion of formation of impurities | Pass (10-Jan-2012) |
| 48696901 | | Villard, I. (2011) Product Specific Chemistry for Effipro Plus Topical Solution for Dogs. Project Number: VIRBAC/104/11/3. Unpublished study prepared by Virbac. 40p. | 830.1750/Certified limits | Pass (10-Jan-2012) |
| 48696902 | | Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)": Final Report. Project Number: D34892. Unpublished study prepared by Harlan Laboratories, Ltd. 24p. | 830.6302/Color | Pass (10-Jan-2012) |
| 48696902 | | Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)": Final Report. Project Number: D34892. Unpublished study prepared by Harlan Laboratories, Ltd. 24p. | 830.6303/Physical state | Pass (10-Jan-2012) |
| 48696902 | | Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)": Final Report. Project Number: D34892. Unpublished study prepared by Harlan Laboratories, Ltd. 24p. | 830.6304/Odor | Pass (10-Jan-2012) |
| 48696903 | | Habeck, C. (2011) 104.11: Determination of Oxidation / Reduction (Chemical Incompatibility): Final Report. Project Number: D34870. Unpublished study prepared by Harlan Laboratories, Ltd. 28p. | 830.6314/Oxidizing or reducing action | Pass (10-Jan-2012) |
| 48696904 | | Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "Flash Point": Final Report. Project Number: D34881. Unpublished study prepared by Harlan Laboratories, Ltd. 29p. | 830.6315/Flammability | Pass (10-Jan-2012) |
| 48696905 | | Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "pH": Final Report. Project Number: D34868. Unpublished study prepared by Harlan Laboratories, Ltd. 27p. | 830.7000/pH | Pass (10-Jan-2012) |
| 48696906 | | Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "Viscosity": Final Report. Project Number: D34846. Unpublished study prepared by Harlan Laboratories, Ltd. 29p. | 830.7100/Viscosity | Pass (10-Jan-2012) |
| 4869 6 907 | | Habeck, C. (2011) 104.11: Determination of the Physico-Chemical Property "Relative Density": Final Report. Project Number: D34857. Unpublished study prepared by Harlan Laboratories, Ltd. 30p. | 830.7300/Density/relative density | Pass (10-Jan-2012) |
| 48696908 | | Zepperitz, C. (2011) (Effipro Plus Topical Solution for Dogs): Quantification of the Active Ingredients Fipronil and Pyriproxyfen in Five Batches by Validated Methods: Final Report. Project Number: D34802. Unpublished study prepared by Harlan Laboratories Ltd. 56p. | 830.1700/Preliminary analysis | Pass (10-Jan-2012) |

Decision#: (459013)

| Chemical: P | YRIPROXYFEN | PC Code: 129032 |
|--|--|--|
| MRID No. | Citation in OSRI | Selected Endocrine Related Findings |
| 42178310 43413202 43210501 43413201 | Study Type: Carcinogenicity Classification: Minimum Year: 1991 Species: Mice Strain: Crl:CD-1 (ICR) BR Sex: Male and Female Age at Initiation: 29 days | Dose levels tested: 0, 22, 90 and 410 mg/day in the diet for 78 weeks. Organ weights: No treatment-related changes were seen in absolute or relative weights of the testes, ovaries, and adrenal glands. Histopathology: No treatment-related histopathological lesions were seen in the testes, ovaries, uterus, mammary, thyroid, adrenal or pituitary glands. |
| 42178309 | Study Type: Chronic Toxicity/ Classification: Guideline Year: 1991 Species: Dog Strain: Beagle Sex: Male and Female Age at Initiation: 23-27 weeks | Dose levels tested: 0, 30, 100, 300 and 1000 mg/kg/day the diet for 54 weeks. Organ weights: No treatment-related changes were seen in absolute or relative weights of the testes, prostate, ovaries, uterus, thyroid, adrenal and pituitary glands. Histopathology: No treatment-related histopathological lesions were seen in the testes, epididymides, prostate, ovaries, uterus, vagina, mammary, thyroid, adrenal or pituitary glands. |



UNITED S. ATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C. 20460

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OFFICE OF PRESENTAIN PESTICILES AS: TOXIS SUBSTANCES

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Subject: EPA ID # 067505-G: Ecto Flea & Tick Insecticide With IGR for Adult Dogs and Puppies Older than 8 Weeks - Review of Domestic Animal Safety Study (MRID # 43396408)

> P.C. Nos.: 109701 & 129032 Tox. Chem. Nos.: 652BB Submission No.: \$475155 D.P. Barcode No.: D208877

From:

Guruva B. Reddy, D.V.M., Ph.D. 人工/知识野华

-5/16/95

Saction 4

Toxicology Branch I

Health Effects Division (7509C)

To:

Marion Johnson/Joseph Tavano

Project Manager 10

Registration Division

Thru:

John Doherty, Ph.D.

Acting Section Mead

Section 4, Toxicology Branch I

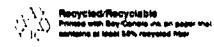
Health Effects Division (75090)

CONCLUSIONS: I.

The domestic animal eafety study is inadequate and Unacceptable and does not estisfy the requirements, of a Series § 86-1 domestic arimal safety study in adult dogs and puppies older than 8 weeks, because of violation of randomization procedures and inadequate number of animale; and lack of pertinent information such as bodyweight gain, food consumption etc., needed for evaluation of mafety of the formulation were not collected or reported.

cc: Doherty

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II. ACTION REQUESTED:

ECTO Development Corporation, Excelsior Springs, MO., has submitted a domestic animal safety study in adult dogs and puppies older than 8 weeks, in support of registration of ECTO Flea & Tick Insecticide With IGR for the control of fleas, ticks and mosquitoes.

III. TOXICOLOGY BRANCE COMMENTS: The following study deficiencies were noted:

- The study did not demonstrate a 3 5 fold safety factor between label usage rate and dermal reactions.
- The animals selected for the study did not appear to be from a healthy stock. This is evidenced from the enythematous reactions in adults prior to application and presence of parvo virus, coccidial, bacterial and helminthic infections in puppies, which compromised study. Any or all treatments or prophylactic measures should be done during the acclimatization period.
- 3. Number of animals used in the study is inadequate. A minimum of 5/sex/age group, at 5 time the recommended dose level for twice the duration of intended use should be employed.
- 4. Data is lacking on bodyweight gains, food consumption, etc... In the absence of which, safety of the treatments cannot be validated.
- 5. Dermal reactions in the vehicle treated were as severe as in the treated group. It appears the dermal reactions in this study were due to vehicle used in the formulation. Therefore, the registrant should consider changing vehicle for safer inactive ingredients.

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Form Approved OMD No. 2079-0069



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. WASHINGTON, D.C. 20460

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| | DA | TA MATRIX | | | |
|---|--|--------------------|---|---------|----------------------------|
| Date: August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | | Page 1 of 6 |
| Applicant's/Registrant's Name & A Virbac SA 1ere avenue 2065 M - LID F-065 t6 Carros, France | Address | | Product: Fipronil Technical | | |
| Ingredient: Fipronil | | | 1 | ······· | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Stam5 | Note |
| Product Chemistry Test Guid | lelines | | | | |
| 830.1550 | Product Identity and Composition | 48095240, 48449201 | Virbae, | OWN | |
| 830.1600 | Description of Materials Used | 48095240 | Virbac | OWN | |
| 830.1620 | Description of Production Process | 48095239 | Virbae | OWN | |
| 830.1650 | Description of Formulation Process | 48095239 | Virbac | OWN | |
| 830.1670 | Description of Forntation of Impurities | 48095240, 48449201 | Virbac | OWN | |
| 830.1700 | Preliminary Analysis | 48095241 | Virbac | OWN | |
| 830.1750 | Certified Limits | 48095240, 48449201 | Virbac | OWN | |
| 830.1800 | Analytical Method | 48095242 | Virbac | OWN | |
| 830.1900 | Submittal of samples | | Virbac | N/A | |
| 830.6302 | Color | 48095240,48095243 | Virbac | OWN | |
| 830.6303 | Physical State | 48095240, 48095243 | Virbac | OWN | |
| 830.6304 | Odor | 48095243 | Virbac | OWN | |
| 830.6313 | Accelerated Storage Stability-Mctal Ions | 48095243 | Virbac | OWN | 1 |
| 830.6314 | Oxidation/reduction | 48095239 | Virbac | OWN | |
| 830.6315 | Flammability | 48095239 | Virbac - | OWN | |
| 830.6316 | Explodability | 48095239 | Virbac | NR | |
| 830.6317 | 1 Yr. Storage Stability | | Vitbac | OWN | See note page 2 |
| Signature | - Jones | | Name and Title Jean-Pascal Marc Corporate Product Innovation Director | | Date August 23, 2011 |

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

Agency internal Use Copy

Form Approved OMB No. 2070-0060



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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| | D | ATA MATRIX | | | |
|---|--|-------------|---|-----------------|----------------------------|
| Date August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | | Page 2 of 0 |
| Applicant's/Registrant's Name & Ad Virbac SA 1erc avenue 2065 M - LID F-06516 Carros, France | dress | | Product: Fipronil Teclutical | | |
| Ingredieut: Fipronil | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 830.6318 | Viscosily | | Virbac | N/A | |
| 830.6319 | Miscibility | | Virbac | N/A | Solid |
| 830.6320 | Corrosion characteristics | | Virbac | OWN | Sec note page 2 |
| 830.6321 | Diclectric breakdown voltage | | Virbac | N/A | Waived |
| 830.7000 | pH | 48095247 | Virbac | OWN | |
| 830.7200 | Melting Point | 48095249 | Virbac | OWN | |
| 830.7300 | Density bulk density or specific gravity | 48095250 | Virbac | OWN | |
| 830.7320 | Particle Stze | | Virbac | N/A | |
| 830.7050 | UV/Visible Spectrum | 48095248 | Virbac | OWN | |
| 830.7370 | Dissociation constant | 48095251 | Virbac | OWN | |
| 830.7520;830.7550; 830.7560 830.7570 | Octanol/water partition coefficient | 48095244 | Virbac | OWN | |
| 830.7840;830.7860 | Solubilily | 48095245 | Virbac | OWN | |
| 830.7950 | Vapor pressure | 48095246 | Virbac | OWN | |
| Signature | man | | Name and Title Jean-Pascal Marc Corporate Product Innovation Direct | or | Date August 23, 2011 |
| EPA Form \$570.35 (0.07) Figureauc and Pance | | ······ | | tontal Hea Cana | |

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Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.

Form Approved OMB No. 2070-0060



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| | | ATA MATRIX | | | |
|---|---|--------------------------------|---|---|----------------------------|
| e: August 23, 2011 | | | EPA Rcg No./File Symbol 87825-R | | Page 3 o. C |
| dicant's/Registrant's Name & Ad pac SA avenue 2065 M - LID 5516 Carros, France | dress | | Product: Fipronil Teclinical | | |
| edient: Fipronil | | | | | |
| deline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| CFR 158.340 Toxicology Da | a Requirements | | | | <u> </u> |
| .1100 | Acute oral toxicity | 42918628; 43235401 43279706 | BASF | OLD | |
| .1200 | Acute dermal toxicity | 42918629 | BASF | OLD | <u> </u> |
| 1,1200 | Acute dermal toxicity | 43235402 | BASF | OLD | |
| 1,1300 | Acute inhalation toxicity | 42918631 | BASF | OLD | |
| 1.2400 | Primary eye irritation | 42918632 | BASF | OLD | |
| 0.2500 | Primary dermal irritation | 42918630 | BASF | OLD | |
| 0.2600 | Dermal sensitization | 42918634 | BASF | OLD | |
| 0.6100 | Acute delayed neurotoxicity | 42918635 | BASF | OLD | |
| 0.6100 | Acute delayed neurotoxicity | 43559501 | BASF | OLD | |
| 0.3100 | 90-day oral toxicity - rodent | 42918643 | BASF | OLD | |
| 0.3150 | 90-day oral toxicity - nonrodent | 42918642 | BASF | OLD | |
| 0.3200 | 21-day derinal toxicity | 42918644 | BASF | OLD | |
| 0.3250 | 90-day dermal toxicity | DATA GAP | BASF | GAP | *See below |
| 0.6100 | 90-day neurotoxicity - mammal | 43291703 | BASF | OLD | |
| 8 | Neurotoxicity to Rats by Acute Oral Administration | 44431801 | BASF | PAY | |
| | Duine | | Name and Title Jean-Pascal Marc Corporate Product Innovation Director | | Date August 23, 2011 |
| · | Versions Available. Submit only Pager version. | | Jean-Pa | ascal Marc ate Product Innovation Director | ascal Marc |

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| | DA | TA MATRIX | | | : |
|---|---|--|---|-------------------|----------------------------|
| Date August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | Page 4 of 6 | |
| Applicant's/Registrant's Name & A Virbae SA tere avenue 2065 M - LtD t'-06516 Carros, France | ddress | | Product: Fiprouil Technical | | |
| Ingredient: Fipronil | | | *************************************** | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| | ata Requirements (Continued) | | | | |
| 84-2 | Structural chromosomal aberration | 42918680 | BASF | OLD | |
| 84-2 | Structural chromosomal aberration | 42918653 | BASF | OLD | |
| 84-2 | Other genotoxic effects | 42918651;42918653 43501703 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42918655 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 43253701 | BASF | PAY | |
| 85-1/870.7485 | General metabolism | 43737308 | BASF | OLD | T |
| 85-1/870.7485 | General metabolism | 42918654 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42977904 | BASF | OLD | <u> </u> |
| 85-1/870.7485 | General metabolism | 43253701 | BASF | OLD | |
| 85-2/870.7600 | Dermal penetration | 43737308 | BASF | PAY | |
| 85-7/870.7600 | Immunotoxicity | DATA GAP | | GAP | *See below |
| 40 CFR 158,490 Wildlife and | Aquatic Organisms Data Requirements | | | OLD | |
| 71-1/850.2100 | Avian oral LD 50 - mallard or bobwhite | 42918617 42918616 | BASF | QLD | |
| 72-1/850,1075 | Freshwater fish LC 50 – rainbow or bluegili | 42918624;42918673; 42918674;42977902 43279703;43291718 | BASF | OLD OLD OLD | |
| Signature | | t consider. | Name and Title Jean-Pascal Marc Corporate Product Innovation Director | | Date August 23, 2011 |

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| | | DATA MATRIX | | | |
|----------------------------|-----------------------------|---------------|---|--------|----------------------------|
| Datc: August 23, 2011 | | | EPA Reg. No./File Symbol 87825-R | | Page 5 of C |
| Virbac SA | | | Product: Fipronil Teelmical | | |
| lere avenue 2065 M - LID | | | | | |
| F-06516 Carros, France | | ······ | | | <u> </u> |
| Ingredient: Fipronil | Culture Cont. Name | LADID Marchan | G.A. ista | Ctatur | Note: |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note " |
| 83-1/870.4100 | Chronic feeding - roden! | 42918648 | BASF | OLD | |
| 83-1/870.4100 | Chronic feeding - nonrodent | 42918645 | BASF | OLD | - |
| 83-1/870.4100 | Chronic feeding - nonroden! | 43402802 | BASF | PAY | |
| 83-2/870.4200 | Oncogenicity - mouse | 42918649 | BASF | OLD | |
| 83-2/870.4200 | Oncogenicity - mouse | 43501702 | BASF | PAY | |
| 83-2/870.4200 | Oncogenicity - rat | 42918648 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rabbit | 42918646 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rat | 42977903 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rat | 44275001 | BASF | PAY | |
| 83-6/870.6300 | Developmental neurotoxicity | 44039002 | BASF | PAY | 1 |
| 83-4/870.3800 | Reproduction | 42918647 | BASF | OLD | |
| 84-2/870.5100 | Gene inutation | 42918652 | BASF | OLD | 1 |
| 84-2/870.5100 | Gene mutation | 42918679 | BASF | OLD | T |
| 84-2/870.5100 | Gene mutation | 43291716 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291717 | BASF | OLD | 1 |
| 84-2/870.5100 | Gene mutation | 43291721 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291722 | BASF | OLD | |
| 84-2/870.5100 | Gene mulation | 43401102 | BASF | OLD | <u> </u> |
| Signature | | | Name and Title Jean-Pascal Mare Corporate Product Innovation Direct | | Date August 23, 2011 |

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| | DA | TA MATRIX | | | ~ |
|---|---|---------------------|---|--------|--------------------|
| Date: August 23, 2011 | | | EPA Reg. No./File Symbol 87825-R | | Page 6 of 6 |
| Applicant's/Registrant's Name & Addr Virbae SA Iere avenue 2065 M - LID F-06516 Carros, France | ess | | Product: Fipronil Technical | - | |
| Ingredient: Fipronil | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note: " |
| 72-2/850.1010 | Acute LC 50 freshwater invertebrates (Daphnia magna) | 42918625 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daphnia magna) | 42918669 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daphnia magna) | 42918671 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Dap/mia magna) | 43291719 | BASF | OLD | |
| 835.21 0 | Hydrolysis | 42977905 | BASF | OLD | |
| 40 CFR 158.390 Reentry Protection Data Requirements | | | | | |
| 133-3 | Dermal exposure - Fipronil | 44433302 | Merial | PAY | |
| 133-4 | Inhalation exposure - Fipronil | 44433302 | Merial | PAY | |
| 132-1 | Dislodgeable residue dissipation - Fipronil | 44531203 | Merial | PAY | |
| N/A | Dermal and inhalation exposure of commercial pet groomers (Spot) - Fipronil | 44433303 | Merial | PAY | |
| N/A | Analytical method for exposure studies - Fipronil | 44433308 | Merial | PAY | |
| Signature | <u></u> | We dead to the con- | Name and Title Jean-Paseal Marc Corporate Product Innovation Director | r. | August 23, 2011 |

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^{*} Pursuant to 40 CFR 152.96 (c), Virbac hereby certifies that Virbac has no basis to believe that this requirement is not a data gap and, further, that Virbac has sent by certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any vatid study that would fulfill this data requirement. Once this 60-day period expires, Virbac witt update the Agency as to the information, if any, Virbac receives in response to this "data gap" letter.



December 20, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject:

EFFIPRO® PLUS Topical Solution for Dogs (EPA File Symbol 2382-TBA);

New Product Application.

Dear Mr. Gebken,

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX 76137, (Company Number 2382)) is hereby submitting an application to register the spot-on pesticide product EFFIPRO® PLUS Topical Solution for Dogs.

This product contains the active ingredients fipronil and pyriproxifen and is intended to control fleas, ticks, mosquitoes, and other pests on dogs only.

Pyriproxyfen itself is registered alone and in combination with other active ingredients in numerous end use products for spot-on insect growth regulator use on dogs.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Offer to Pay letters are being sent to the submitters of data cited in Virbac's application that were originally submitted within the past 15 years.

Below is a list of the components included with this application:

- 1. Cover Letter;
- 2. Transmittal Document;
- 3. Application for Pesticide Form 8570-1;
- 4. Confidential Statement of Formula-2 Copies;
- 5. Data Matrix Form 8570-4; (EUP and TGAI);
- 6. Certification of Data Citation Form 8570-34;
- 7. Proposed Label 5 copies;
- 8. 3 copies of bound PR 86-5 compliant study reports supporting registration;
- 9. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
- 10. Letter of Self-certification of Child-Resistant Packaging;
- 11. Formulator's Exemption Form 8570-27; and
- 12. Copy of PRIA Check for category R-310 (\$4807).

Child-Resistant Packaging

EFFIPRO® PLUS Topical Solution for Dogs and will be marketed in single dose unit applicators in packages of 1, 3, 6, and 36. These single dose applicators for the 0.67 ml, 1.34 ml, 2.68 ml, and 4.02 ml dose sizes have been previously tested, and CRP certification has been accepted by EPA. All relevant test data supporting self-certification have been reviewed are and cited in the attached Data Matrix. A self-certification letter is also attached.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this product. Consequently, please find a copy of one previously submitted check in the amount of \$4807 to cover the PRIA fee.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

Craig Parks, MS, DVM

Craig tach

Vice President, Research & Development

Virbac Animal Health, Inc.

Attachments

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac, Inc. (EPA Company Number 2382) P.O. Box 162059 Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use pro namely EFFIPRO® PLUS Topical Solution for Dogs. Effipro® EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredients Fipronil and Pyriproxyfen.

SUBMITTAL DATE:

December 20, 2011

| Volume | Study Title | MRID No. |
|--------|---|----------|
| l | Administrative Materials | |
| | Effipro® Plus Topical Solution for Dogs | |
| | Group A Product Chemistry | |
| 2 | OPPTS 830.1550, 830.1750, 830.1600, 830.1620, 830.1650, 830.1670 EFFIPRO® PLUS Topical Solution for Dogs | 48696901 |
| | Group B Product Chemistry | |
| 3 | OPPTS 830.6302, 830.6303, 830.6304 Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)" | 48696902 |
| . 4 | OPPTS 830.6314 Determination of Oxidation / Reduction (Chemical Incompatibility) | 48696903 |
| 5 | OPPTS 830.6315 Determination of the Physico-Chemical Property "Flash Point" | 48696904 |
| 6 | OPPTS 830.7000 Determination of the Physico-Chemical Property "pH" | 48696905 |
| 7 | OPPTS 830.7100 Determination of Physico-Chemical Property "Viscosity" | 48696906 |
| 8 | OPPTS 830,7300 Determination of the Physico-Chemical Property "Relative Density" | 48696907 |

| Volume | Study Title | MRID No. |
|--------|--|-----------|
| 9 | OPPTS 830.1700, 830.1800 | |
| | Quantification of the Active Ingredients Fipronil and Pyriproxyfen | 48696908 |
| | in Five Batches by Validated Methods | |
| 10 | OPPTS 830.1800 | |
| | Enforcement Analytical Method – Quantification of the Active | 48696909 |
| | Ingredients Fipronil and Pyriproxyfen | |
| | Acute Toxicity | |
| 11 | OPPTS 870. 1100 | 49606040 |
| | Acute Oral Toxicity Study in Rats – Up-and-Down-Procedure | 48696910 |
| 12 | OPPTS 870.1200 | |
| | Acute Dermal Toxicity Study in Rats | 48696911 |
| 13 | OPPTS 870.2400 | 48696912 |
| | Acute Eye Irritation Study in Rabbits | 400909.15 |
| 14 | OPPTS 870.2500 | 48696913 |
| | Acute Dermal Irritation Study in Rabbits | |
| 15 | OPPTS 870.2600 | 48696914 |
| | Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test | 40000314 |
| | Product Performance | |
| 16 | OPPTS 810.3300 | |
| | Summary of Efficacy Data for EFFIPRO® PLUS Topical Solution | 48696915 |
| | for Dogs | |
| | Product Safety | |
| 17 | OPPTS 870.7200 | 400000 |
| į | Summary of Companion Animal Safety Data for EFFIPRO® | 48696916 |
| | PLUS Topical Solution for Dogs | |

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| | \mathbf{D} A | ATA MATRIX | | | |
|--|--|-----------------|---|--------|-----------------------------|
| Date: December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | |
| Applicant's/Registrant's Name & | Address | | Product: | | |
| Virbae Al-l, lue. | | | | | |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | R DOGS | |
| Fort Worth TX 76161 Ingredient: Fipronil, Pyriproxyfe | | | | ····- | <u> </u> |
| Guideline Reference Number | Guideline Study Name | MRtD Number | Submitter | Status | Note |
| Product Chemistry Test Gu | | 1 MIXID MINIOCI | Submitter | Dialus | Note |
| 830.1550 | Product Identity and Composition | New Submission | Virbac AH, Inc. | OWN | |
| 830.1600 | Description of Materials Used | New Submission | Virbac AH, Inc. | OWN | |
| 830.1620 | Description of Production Process | New Submission | Virbae AH, Inc. | OWN | |
| 830.1650 | Description of Formulation Process | New Submission | Virbac AH, Inc. | OWN | |
| 830.1670 | Description of Formation of Impurities | New Submission | Virbac AH, Inc. | OWN | |
| 830,1700 | 5-Batch Analysis | New Submission | Virbac AH, Inc. | OWN | |
| 830.1750 | Certified Limits | New Submission | Virbac AH, Inc. | OWN | |
| 830,1800 | Analytical Method | New Submission | Virbac AH, Inc. | OWN | - |
| 830.6302 | Color | New Submission | Virbac AH, Inc. | OWN | |
| 830.6303 | Physical State | New Subinission | Virbac AH, Inc. | OWN | |
| 830.6304 | Odor | New Submission | Virbac AH, Inc. | OWN | |
| 830,6313 | Metal Stability | | Virbae AH, Inc. | NR | |
| 830.6314 | Oxidation/reduction | New Submission | Virbac AH, Inc. | OWN | |
| 830.6315 | Flammability | New Submission | Virbac AH, Inc. | OWN | |
| 830.6316 | Explodability | | Virbae AH, Inc. | NR | |
| 830.6317 | Storage stability | To be conducted | Virbac AH, Inc. | OWN | |
| Signature Leavy Kah | | | Name and Title Craig Parks Vice President, Research & Development | | Date Decembe 2C, 2011 |

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| | DA | TA MATRIX | | | |
|--|--|--|--|--------|----------|
| Date December 20, 2011 | | | EPA Reg. No./File Symbol 2382-fBA | | |
| Applicant's/Registrant's Name & A | ddress | | Product: | | |
| Virbae AH, Inc | | | | | |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | R DOGS | |
| Fon Worth TX 76161 | | | | | |
| Ingredient: Fipronil, Pyriproxyfen Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 830.7100 | Viscosity | New Submission | Virbac AH, Inc. | OWN | |
| 830.6319 | Miscibility | ************************************** | Virbac AH, Inc. | NR | |
| 830.6320 | Corrosion characteristics | To be conducted | Virbac AH, Inc. | OWN | |
| 830.6321 | Dielectrie breakdown voltage | | Virbac AH, Inc. | NR | |
| 830.7000 | pН | New Submission | Virbac AH, Inc. | OWN | |
| 830.7300 | Density, bulk density, or specific gravity | New Submission | Virbac AH, Inc. | OWN | |
| 830.7320 | Particle Size distribution | | Virbae AH, Inc. | NR | |
| 40 CFR 158.340 Toxicology D | ata Requirements | ······································ | | | |
| 870.1100 | Acute oral toxicity | New Submission | Virbac AH, Inc. | OWN | |
| 870.1200 | Acute dermal toxicity | New Submission | Virbac AH, Inc. | OWN | |
| 870.1300 | Acute inhalation toxicity | Waiver requested | Virbac AH, Inc. | | |
| 870.2400 | Primary eye trritation | New Submission | Virbac AH, Inc. | OWN | |
| 870.2500 | Primary dermal irritation | New Submission | Virbac AH, Inc. | OWN | |
| 870.2600 | Dermal sensitization | New Submission | Virbac AH, Inc. | OWN | |
| Signature | | | Name and Title | | Date |
| 1 1 | | | Craig Parks | | December |
| Caig hah | | | Vice President, Research & Development | | 20, 2011 |
| cary | | | | | |
| | | | | | 1 |

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| | | DATA MATRIX | | | |
|---|--|---|--|---------|-------------|
| Date: December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | Page 3 of 9 |
| Applicant's/Registrant's Nante & A | ddress | | Product: | | |
| Virbae AH, Inc | | | | | |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | OR DOGS | |
| Fort Worth TX 76161 | | | | | <u> </u> |
| Ingredient: Fipronil, Pyriproxyfen Guideline Reference Number | Grideline Study Name | MRID Number | Submitter | Status | Note |
| Efficacy and Safety Data | Gildeline Study (Value | MAD Munder | Submitter | Status | Note |
| 870.7200 | Dog safety | 43444905 | Merial | OLD | |
| 370.7200 370.7200 | Dog safety Dog safety | 43577711 | Merial | OLD | |
| 370.7200 | Dog safety Dog safety | 43863802 | Merial | OLD | |
| 870.7200 870.7200 | Dog safety Dog safety | 43121110 | Merial | OLD | |
| 870.7200 870.7200 | Dog safety Dog safety | 43121111 | Merial | OLD | |
| | ······································ | *************************************** | | PAY | |
| 370.7200 | Dog safety | 45620507 | Merial | | |
| 370.7200 | Dog safety | 43396408 | Ecto Development Corporation | OLD | |
| 870.7200 | Dog safety | 43612601 | Ecto Development Corporation | OLD | |
| 370.7200 | Dog safcty | 44900902 | Virbac AH, Inc. | OWN | ļ |
| 370.7200 | Dog safety | 44900903 | Virbae AH, Inc. | OWN | |
| 370.7200 | Dog safety | 42178309 | Sumitomo Chemical Company, Ltd. | OLD | |
| 870.7200 | Dog safety | New submission | Virbae AH, Inc. | OWN | ļ |
| 810.3300 | Efficacy | 43121114 | Merial | OLD | |
| 310.3300 | Efficacy | 43121115 | Merial | OLD | |
| 810,3300 | Efficacy | 43121116 | Merial | OLD | ļ |
| 810.3300 | Efficacy | 43 12 1 1 1 7 | Merial | OLD | |
| 810.3300 | Efficacy | 43121118 | Merial | OLD | |
| 810.3300 | Efficacy | 43121119 | Merial | OLD | |
| 810.3300 | Efficacy | 43121120 | Merial | OLD | 1 |
| Signature | | | Name and Title | | Date |
| Cray Lake | | | Craig Parks | | December |
| Lay take | | | Vice President, Research & Development | | 20, 2011 |

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| | | DATA MATRIX | | - | |
|--------------------------------------|----------------------|--|--|-------------|------------------------------|
| Date: December 20, 2011 | | EPA Rcg. No./File Symbol 2382-TBA | | Page 4 of 9 | |
| Applicant's/Registrant's Name & A | ddress | Product: | | | |
| Virbae AH, Inc | | | | | |
| PO Box 162059 Fort Worth TX 76161 | | | EFFIPRO® PLUS TOPICAL SOLUTION | N FOR DOGS | |
| Ingredient: Fipronil, Pyriproxyfen | | | <u> </u> | | · |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Slatus | Nole |
| Efficacy and Safety Data | | | | - Olavor | 71010 |
| 810.3300 | Efficacy | 43121121 | Merial | OLD | |
| 810.3300 | Efficacy | 43121121 | Merial | OLD | |
| 810.3300 | Efficacy | 43121122 | Merial | OLD | ļ |
| 810.3300 | Efficacy | 43577701 | Merial | OLD | |
| | | | | OLD | |
| 810.3300 | Efficacy | 43577712 | Merial | OLD | |
| 810.3300 | Efficacy | 43577713 | Merial | | |
| 810.3300 | Efficacy | 43951701 | Merial | OLD | |
| 810.3300 | Efficacy | 44088901 | Merial | OLD | <u> </u> |
| 810.3300 | Efficacy | 46006002 | Wellmark International | PUBL | <u></u> |
| 810.3300 | Efficacy | 44900904 | Virbac AH, Inc. | OWN | |
| 810.3300 | Efficacy | 45020601 | Virbac Al-I, Inc. | OWN | <u> </u> |
| 810,3300 | Efficacy | Pending; submitted with Effipro Phys Cat Application | | OWN | |
| 810.3300 | Efficacy | New submission | | OWN | |
| Signature | | | Name and Title Craig Parks Vice President, Research & Developmen | nt | Date December 20, 2011 |

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| | | DATA MATRIX | | | · |
|---|----------------------|-------------|--|---------|------------------------------|
| Date December 20, 2011 Applicant's/Registrant's Name & Address Virbac Al4, Inc PO Box 162059 I'ort Worth TX 76161 | | | EPA Reg. No./File Symbol 2382-TBA | | |
| | | | Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS | | |
| Ingredient: Fipronil, Pyriproxyfen | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 810.3300 | Efficacy | 44942011 | Merial | PAY | |
| 810.3300 | Efficacy | 44942106 | Merial | PAY | |
| 810.3300 | Efficacy | 45612701 | Merial | PAY | |
| 810.3300 | Efficacy | 45618501 | Merial | PAY | |
| 810.3300 | Efficacy | 45620501 | Meria! | PAY | |
| 810.3300 | Efficacy | 45620502 | Merial | PAY | |
| 810.3300 | Efficacy | 45620503 | Merial | PAY | |
| 810.3300 | Efficacy | 45620504 | Merial | PAY | |
| 810.3300 | Efficacy | 45620505 | Merial | PAY | |
| 810.3300 | Efficacy | 45620506 | Merial | PAY | |
| 810.3300 | Efficacy | 45628101 | Merial | PAY | |
| 810.3300 | Efficacy | 45628102 | Merial | PAY | |
| 810.3300 | Efficacy | 45628103 | Merial | PAY | |
| 810.3300 | Efficacy | 45628104 | Merial | PAY | |
| 810.3300 | Efficacy | 45628105 | Merial | PAY | |
| 810.3300 | Efficacy | 45628201 | Merial | PAY | |
| 810.3300 | Efficacy | 45866901 | Merial | PAY | |
| 810.3300 | Efficacy | 45866902 | Merial | PAY | |
| 810.3300 | Efficacy | 46019201 | Merial | PAY | |
| 810,3300 | Efficacy | 46019202 | Merial | PAY | |
| Signature Lang Kah | | | Name and Title Craig Parks Vice President, Research & Deve | dopment | Date December 20, 2011 |

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| | DAT | A MATRIX | | | |
|-------------------------------|---|-----------------------------------|---|-------------|------------------------------|
| Date: December 20 | , 2011 | EPA Reg. No./File Symbol 2382-TBA | | Page 6 of 9 | |
| | nt's Name & Address | | Product: | | |
| Virbae AH, luc | | | | | |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | R DOGS | |
| Fort Worth TX 7616 | | | | | <u></u> |
| Ingredient: Fipronil, | | MRID Number | | T C(| 1 31-4- |
| Guideline Reference Number | Guideline Study Name | WKID Nimber | Submitter | Status | Note |
| Child Resistant F | Packaging | | | | |
| 40 CFR 157 | Evaluation of the 3 mi Applicator Tube with 1.34 mi water, 1 applicator tube test for Child-Resistant Effectiveness | 48095221 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Child-Resistant Effectiveness | 48095222 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Child-Resistant Effectiveness | 48095223 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Schior-Use Effectiveness | 48095224 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 iiil Applicator Tube with 1.34 ml water, 6 applicators tube test for Senior-Use Effectiveness | 48095225 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 mi Applicator Tube with 1.34 ml water, 36 applicators tube test for Senior-Use Effectiveness | 48095226 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68tnl water, 1 applicator tube test for Child-Resistant Effectiveness | 48095227 | Virbae AH, Inc. | OWN | |
| Signature Conj to | | | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 |

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| | DATA | MATRIX | | | |
|--|---|-------------|---|---|------------------------------|
| Date: December 16, | 2011 | | EPA Reg. No./File Syntbol 2382-TBA | | |
| Applicant's/Registra Virbae AH, Inc | nt's Name & Address | | Product: | | |
| PO Box 162059 Fort Worth TX 7616 | ia | | EFFIPRO® PLUS TOPICAL SOLUTION | FOR DOGS | |
| Ingredienl: Fipropil, | Pyriproxyfen | | | *************************************** | |
| Guideline Reference Number | Guideline Study Nante | MRID Number | Submitter | Status | Note |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Child-Resistant Effectiveness | 48095228 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Child-Resistant Effectiveness | 48095229 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48095230 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Senior-Use Effectiveness | 48095231 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Senior-Use Effectiveness | 48095232 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 1 applicator tube test for Child-Resistant Effectiveness | 48095233 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness | 48095234 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 applicators tube test for Child-Resistant Effectiveness | 48095235 | Virbac AH, luc. | OWN | |
| Signature Lang Rah | | | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 |

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| | DAT | A MATRIX | | | |
|---|---|-------------|---|-------------|------------------------------|
| Date: December 20, | 2011 | ···· | EPA Reg. No./File Symbol 2382-TBA | Page 8 of 9 | |
| Applicant's/Regisfrant Virbae AH, Inc PO Box 162059 Fort Worth TX 7616 | nt's Name & Address | | Product: EFFIPRO® PLUS TOPICAL SOLUTION FO | | |
| Ingredient: Fipronil, | | | | | <u> </u> |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Sfaius | Noic |
| 40 CFR 157 | Evaluation of the 1 ml applicator tube with 0.67 ml water, 1 applicator tube test for Child-Resistant Effectiveness | 48410001 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48410002 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1:nl applicator tube with 0.67 ml water, 6 applicator tube test for Child-Resistant Effectiveness | 48410003 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Senior-Use Effectiveness | 48410004 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Child-Resistant Effectiveness | 48410005 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1 nl applicator tube with 0.67 ntl water, 36 applicator tube test for Senior-Use Effectiveness | 48410006 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 inl water, 3 applicator tube test for Child-Resistant Effectiveness | 48410007 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Senior-Use Effectiveness | 48410008 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3nd applicator tube with 1.34 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410009 | Virbac Al·I, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Senior-Use Effectiveness | 48410010 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410011 | Virbae AH, Inc. | OWN | |
| Signature Lady Rah | | | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 |

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| | DAT | 'A MATRIX | | | |
|-----------------------|--|---|--|-------------|-------------------|
| Date December 20, | 2011 | EPA Reg. No./File Symbol 2382-TBA | | Page 9 of 9 | |
| Applicant's/Registra | int's Name & Address | | Product: | | |
| Virbae AH, Inc | | | | | |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUTION I | FOR DOGS | |
| Fort Worth TX 7616 | VIII | <u> </u> | | | <u> </u> |
| Ingredient: Fipronil, | | Name of the state | 181 | 1 2 | 1 37 |
| Guideline | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Reference Number | First -4: | 40410010 | 37:1 - 417 1 | OU/NI | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Senior-Use Effectiveness | 48410012 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410013 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1 ml applicator tube with 4.02 ml water, 3 applicator tube test for Senior-Use Effectiveness | 48410014 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48410015 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 36 applicator tube test for Seuior-Use Effectiveness | 48410016 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6ml applicator tube with 4.02 ml water, 6 applicator tube test for Senior-Use Effectiveness | 48410017 | Virbac AH, Inc. | OWN | |
| Signature | | | Name and Title | | Date |
| Craig Kah | | | Craig Parks Vice President, Research & Development | | December 20, 2011 |

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| Date: August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | | |
|---|--|---|---|--------|---------------------------|
| Applicant's/Registrant's Name & A | ddress | | Product: Fipronil Technical | | Page 1 of 6 |
| Virbac SA | | | | | |
| lere avenue 2065 M - LID | | | | | |
| F-06516 Carrns, France | | | | | |
| Ingredient: Fipronil Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| | | Wild Number | Submitter | Status | Note |
| Product Chemistry Test Guid 830.1550 | Product Identity and Composition | 48095240, 48449201 | Virbac. | OWN | |
| 830.1600 | Description of Materials Used | 48095240 | Virbac | OWN | |
| 830.1620 | Description of Production Process | 48095239 | Virbac | OWN | |
| 830.1650 | Description of Formulation Process | 48095239 | Virbac | OWN | |
| 830.1670 | Description of Formation of Impurities | 48095240, 48449201 | Virbac | OWN | |
| 830.1700 | Preliminary Analysis | 48095241 | Virbac | OWN | |
| 830.1750 | Certified Limits | 48095240, 48449201 | Virbac | OWN | |
| 830.1800 | Analytical Method | 48095242 | Virbae | OWN | |
| 830.1900 | Submittal of samples | *************************************** | Virbac | N/A | |
| 830.6302 | Color | 48095240, 48095243 | Virbac | OWN | |
| 830.6303 | Physical State | 48095240, 48095243 | Virbac | OWN | |
| 830.6304 | Odor | 48095243 | Virbac | OWN | |
| 830.6313 | Accelerated Storage Stability-Metal Ions | 48095243 | Virbac | OWN | |
| 830.6314 | Oxidation/reduction | 48095239 | Virbac | OWN | |
| 830.6315 | Flammability | 48095239 | Virbac | OWN | |
| 830.6316 | Explodability | 48095239 | Virbae | NR | |
| 830.6317 | l Yr. Storage Stability | | Virbac Name and Title | OWN | See note page 2 |
| Signature | | | Name and Title Jean-Pascal Marc Corporate Product Innovation Director | - | Date August 23 2011 |

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| | D. | ATA MATRIX | | ···· | |
|--|--|-------------|---------------------------------|--------|-----------------------------|
| Date August 23, 201 t | | | EPA Reg No./File Symbol 87825-R | | |
| Applicant's/Registrant's Name & Add Virbae SA tere avenue 2065 M - LID F-06516 Carros, France | iress | | Pruduct; Fipronii Technical | | |
| Ingredient: Fipronil | | | | | |
| Guideline Reference Number | Guideline Study Name | MRtD Number | Submitter | Status | Note |
| 830.6318 | Viscosity | | Virbac | N/A | |
| 830.6319 | Miscibility | | Virbac | N/A | Solid |
| 830.6320 | Corrosion characteristics | | Virbac | OWN | See note page 2 |
| 830.6321 | Dielectric breakdown voltage | | Virbac | N/A | Waived |
| 830,7000 | pH | 48095247 | Virbac | OWN | |
| 830.7200 | Melting Point | 48095249 | Virbae | OWN | |
| 830.7300 | Density bulk density or specific gravity | 48095250 | Virbac | OWN | Į |
| 830.7320 | Particle Size | | Virbac | N/A | |
| 830.7050 | UV/Visible Spectrum | 48095248 | Virbac | OWN | |
| 830.7370 | Dissociation constant | 48095251 | Virbac | OWN | |
| 830.7520;830.7550; 830.7560 830.7570 | Octanol/water partition coefficient | 48095244 | Virbac | OWN | |
| 830.7840;830.7860 | Solubility | 48095245 | Virbac | OWN | |
| 830.7950 | Vapor pressure | 48095246 | Virbac | OWN | |
| Jean-Pascal Marc A | | | | | Date August 23, 20t i |

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Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.

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|---|---|--------------------------------|--|----------|----------------------------|
| Date: August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | | Page 3 of 6 |
| Applicant's/Registrant's Name & A | ddress | | Product: Fipronil Technical | | |
| Virbac SA | | | | | |
| lere avenue 2065 M - LID | | | | | |
| F-06516 Carros, France Ingredient: Fipronil | | | | | |
| Guideline Reference Number | Guideline Study Name | MR(D Number | Submitter | Status | Note |
| 40 CFR 158.340 Toxicology D. | | WKKD PKUMOCI | Buomaci | Biaius | 1 11010 |
| 870.1100 | Acute oral toxicity | 42918628; 43235401 43279706 | BASF | OLD | |
| 870.1200 | Acute dermal toxicity | 42918629 | BASF | OLD | |
| 870.1200 | Acute dermal toxicity | 43235402 | BASF | OLD | |
| 870.1300 | Acute inhalation toxicity | 42918631 | BASF | OLD | |
| 870.2400 | Primary eye irritation | 42918632 | BASF | OLD | |
| 870.2500 | Primary definal irritation | 42918630 | BASF | OLD | |
| 870.2600 | Dermal sensitization | 42918634 | BASF | OLD | |
| 870.6100 | Acute delayed neurotoxicity | 42918635 | BASF | OLD | |
| 870.6100 | Acute delayed neurotoxicity | 43559501 | BASF | OLD | |
| 870.3100 | 90-day oral toxicity - rodent | 42918643 | BASF | OLD | |
| 870.3150 | 90-day oral toxicity - nonrodent | 42918642 | BASF | OLD | |
| 870.3200 | 21-day dermal toxicity | 42918644 | BASF | OLD | |
| 870.3250 | 90-day dermal toxicity | DATA GAP | BASF | GAP | *See below |
| 870.6100 | 90-day neurotoxicity - maininal | 43291703 | BASF | OLD | |
| 81-8 | Neurotoxicity to Rats by Acute Oral Administration | 44431801 | BASF | PAY | |
| Signature | | | Name and Title Jean-Pascal Mare Corporate Product Innovation Directo | <u>I</u> | Date August 23, 2011 |

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| | DA | TA MATRIX | | *************************************** | |
|--|---|--|--|---|------------------------------|
| Date August 23, 2011 | | | EPA Rcg No./File Symbol 87825-R | | Page 4 of 6 |
| Applicant's/Registrant's Name & A Virbac SA Jere avenue 2065 M - L1D | | | Product: Fipronil Technical | | |
| F-06516 Carros, France | | | | | |
| Ingredient: Fipronil | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 40 CFR 158.340 Toxicology D | ata Requirements (Continued) | | | | |
| 84-2 | Structural chromosomal aberration | 42918680 | BASF | OLD | |
| 84-2 | Structural chromosomal aberration | 42918653 | BASF | OLD | |
| 84-2 | Other genoloxic effects | 42918651;42918653 43501703 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42918655 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 43253701 | BASF | PAY | |
| 85-1/870.7485 | General metabolism | 43737308 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42918654 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42977904 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 43253701 | BASF | OLD | |
| 85-2/870.7600 | Dermal penetration | 43737308 | BASF | PAY | |
| 85-7/870.7600 | liminumotoxicity | DATA GAP | | GAP | *See below |
| 40 CFR 158,490 Wildlife and | Aquatic Organisms Data Requirements | | | OLD | |
| 71-1/850.2100 | Avian oral LD 50 - mallard or bobwhite | 42918617 42918616 | BASF | OLD | |
| 72-1/850.1075 | Freshwater fish LC 50 – rainbow of bluegill | 42918624;42918673; 42918674;42977902 43279703;43291718 | BASF | OLD OLD | |
| Signature | | | Name and Tilk Jean-Pescal Mare Corporate Product Innovation Director | · · · · · · · · · · · · · · · · · · · | Date August 23, - 2011 |

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| | | DATA MATRIX | | | |
|--|-----------------------------|-------------|---|--------|----------------------------|
| Date: August 23, 2011 | | | EPA Reg. No./File Symbol 87825-R | | Page 5 of 6 |
| Vírbac SA | | | Product: Fipronil Technical | | |
| For avenue 2065 M - LID | | | | | |
| F-06516 Carros, France Ingredient: Fipronil | | | | | <u> </u> |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 83-1/870.4100 | Cltronic feeding - rodent | 42918648 | BASF | OLD | 11000 |
| 83-1/870.4100 | Chronic feeding – nonrodeut | 42918645 | BASF | OLD | |
| 83-1/870.4100 | Chronic feeding – nonrodent | 43402802 | BASIF | PAY | |
| 83-2/870.4200 | Oncogenicity mouse | 42918649 | BASF | OLD | |
| 83-2/870.4200 | Oncogenicity - mouse | 43501702 | BASF | PAY | |
| 83-2/870.4200 | Oncogenicity - rat | 42918648 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity – rabbit | 42918646 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rat | 42977903 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rat | 44275001 | BASF | PAY | |
| 83-6/870.6300 | Developmental neurotoxicity | 44039002 | BASF | PAY | |
| 83-4/870.3800 | Reproduction | 42918647 | BASF | OLD | 1 |
| 84-2/870.5100 | Gene mutation | 42918652 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 42918679 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291716 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291717 | BASF | OLD | |
| 84-2/870.5100 | Gene instation | 43291721 | BASF | OLD | |
| 84-2/870,5100 | Gene mutation | 43291722 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43401102 | BASF | OLD | |
| Signature | | | Name and Title Jean-Pascal Mare Corporate Product Innovation Dire | ector | Date August 23, 2011 |

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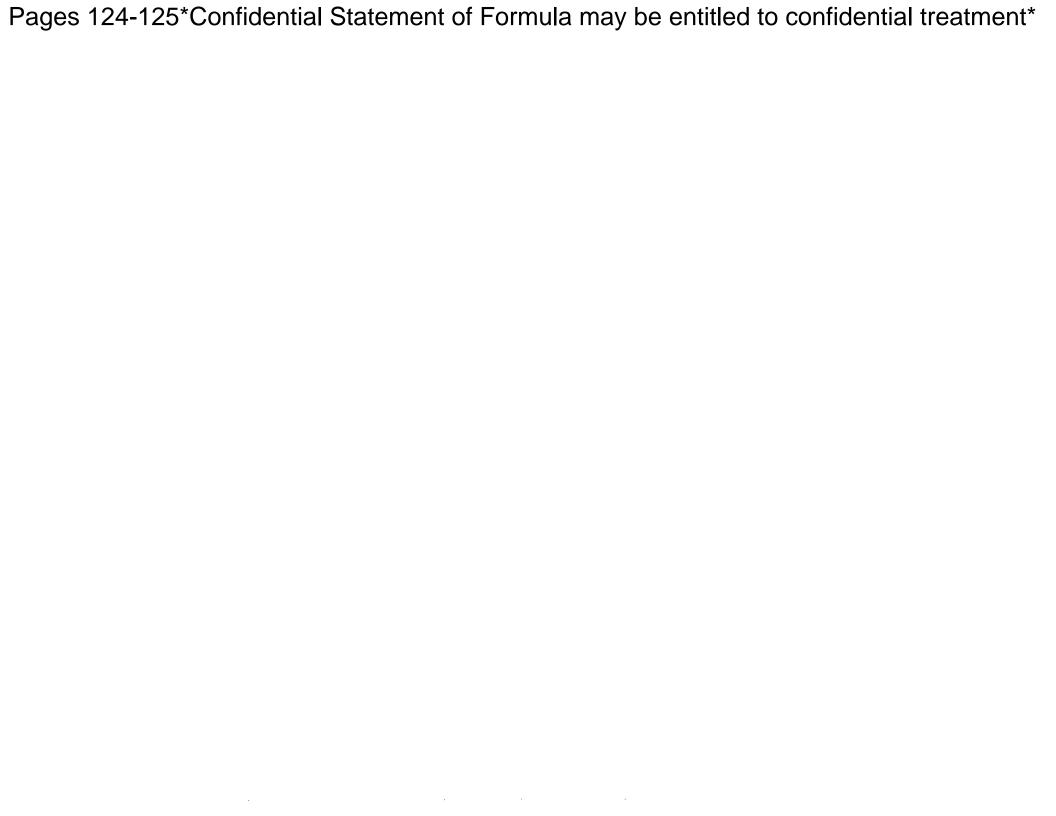
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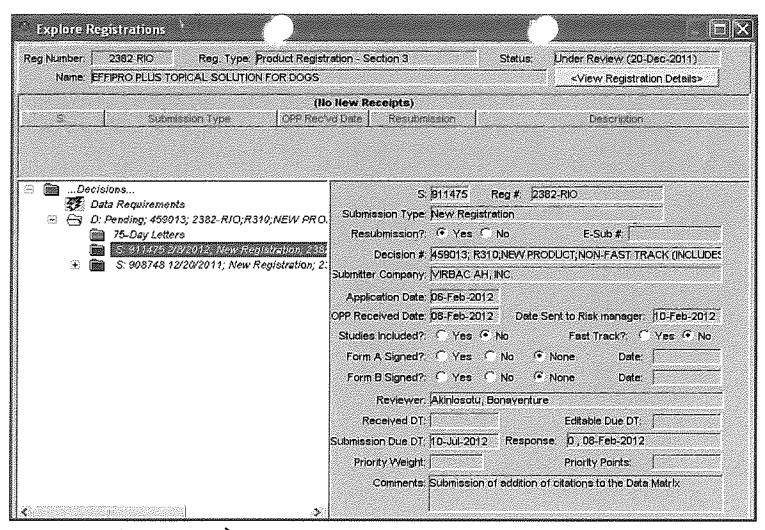
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| | DA | TA MATRIX | | | |
|---|---|-------------|---|--------|--------------------|
| Date: August 23, 2011 | | | EPA Reg. No/File Symbol 87825-R | | Page 6 of 6 |
| Applicant's/Registrant's Name & Addr Virbae SA lere avenue 2065 M - LHD F-06516 Carros, France | ess | | Product: Fipronil Technical | | |
| Ingredient: Fipronil | | | | | 1 |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 72-2/850.1010 | Acute LC 50 freshwater invertebrates (Daphnia magna) | 42918625 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daphnia magna) | 42918669 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daplinia magna) | 42918671 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daphnia magna) | 43291719 | BASF | OLD | |
| 835.2110 | Hydrolysis | 42977905 | BASF | OLD | |
| 40 CFR 158.390 Reentry Protection Data Requirements | | | | | |
| 133-3 | Dermal exposure - Fipronil | 44433302 | Merial | PAY | |
| 133-4 | Inhalation exposure - Fipronil | 44433302 | Merial | PAY | |
| 132-1 | Dislodgeable residue dissipation - Fipronil | 44531203 | Merial | PAY | |
| N/A | Dermal and inhalation exposure of commercial pet groomers (Spot) - Fipronti | 44433303 | Merial | PAY | |
| N/A | Analytical method for exposure studies - Fipronil | 44433308 | Merial | PAY | |
| Signature | | | Name and Title Jean-Pascal Marc Curporate Product Innovation Director | | August 23, 2011 |

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^{*} Pursuant to 40 CFR 152.96 (c), Virbae hereby certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbae will untilete the Agency as to the information, if any, Virbae receives in response to this "data gap" tetter.





· Resubstitut Periser Dotter Matrix per Roz (CRP) request to add "mend or SAME testing".

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| | DA | TA MATRIX | | | |
|--|--|--------------------|---|--------|---------------------------|
| Date: August 23, 2011 | | | EPA Reg No./Pile Symbol 87825-R | | Page 1 of 6 |
| Applicant's/Registrant's Name & A | Address | | Product: Fipronil Technical | | |
| Virbae SA | | | | | |
| Lere avenue 2065 M - LID | | | | | |
| F-06516 Carros, France Ingredient: Fipronil | | | | | <u> </u> |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Product Chemistry Test Guid | K.,,,,, | | | | |
| 830.1550 | Product Identity and Composition | 48095240, 48449201 | Virbac. | OWN | |
| 830.1600 | Description of Materials Used | 48095240 | Virbac | OWN | |
| 830.1620 | Description of Production Process | 48095239 | Virbae | OWN | |
| 830.1650 | Description of Formulation Process | 48095239 | Virbac | OWN | |
| 830.1670 | Description of Formation of Impurities | 48095240, 48449201 | Virbac | OWN | |
| 830.1700 | Preliminary Analysis | 48095241 | Virbac | OWN | |
| 830.1750 | Certified Limits | 48095240, 48449201 | Virbae | OWN | |
| 830.1800 | Analytical Method | 48095242 | Virbaç | OWN | |
| 830.1900 | Submittal of samples | | Virbae | N/A | |
| 830.6302 | Color | 48095240, 48095243 | Virbac | OWN | |
| 830.6303 | Physical State | 48095240, 48095243 | Virbae | OWN | |
| 830.6304 | Odor | 48095243 | Virbac | OWN | |
| 830.6313 | Accelerated Storage Stability-Metal Ions | 48095243 | Virbac | OWN | |
| 830.6314 | Oxidation/reduction | 48095239 | Virbac | OWN | |
| 830.6315 | Flammability | 48095239 | Virbae | OWN | |
| 830.6316 | Explodability | 48095239 | Virbae | NR | |
| 830.6317 | 1 Yr. Storage Stability | | Virbac | OWN | See note page 2 |
| Signature | | | Name and Title Jean-Pascal Marc Corporate Product Innovation Director | | Date August 23 2011 |

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| | D A | ATA MATRIX | | | - 1 |
|--|--|-------------|--|--------|-----------------------------|
| Date August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | | Page 2 of 6 |
| Applicant's/Registrant's Name & Add Virbac SA Icre avenue 2065 M - LID F-06516 Carros, France | iress | | Product: Fipronil Teclinical | | |
| Ingredient: Fipronil | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 830.6318 | Viscosity | | Virbac | N/A | <u> </u> |
| 830.6319 | Miscibility | | Virbae | N/A | Solid |
| 830.6320 | Corrosion characteristics | | Virbac | OWN | See note page 2 |
| 830.6321 | Dielectrie breakdown voltage | | Virbac | N/A | Waived |
| 830,7000 | pH | 48095247 | Virbae | OWN | |
| 830.7200 | Melting Point | 48095249 | Virbae | OWN | |
| 830.7300 | Density bulk density or specific gravity | 48095250 | Virbac | OWN | |
| 830.7320 | Particle Size | | Virbac | N/A | |
| 830.7050 | UV/Visible Spectrum | 48095248 | Virbac | OWN | |
| 830.7370 | Dissociation constant | 48095251 | Virbae | OWN | |
| 830.7520;830.7550; 830.7560 830.7570 | Octanol/water partition coefficient | 48095244 | Virbac | OWN | |
| 830.7840;830.7860 | Solubility | 4809 5245 | Virbae | OWN | |
| 830.7950 | Vapor pressure | 48095246 | Virbae | OWN | |
| Signature | À7 | | Name and Title Jean-Pascal Mare Corporate Product Emovation Director | | Date August 23, 201 (|

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Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.

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| | D | ATA MATRIX | | | |
|--|---|--------------------------------|---|--------|----------------------------|
| Date: August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | | Page 3 of 6 |
| Applicant's/Registraot's Name & A Virbac SA Tere avenue 2065 M - LID | ddress | | Product: Fipronil Technical | | |
| F-06516 Carros, France | ······································ | | | | |
| Ingredient: Fipronil | | NADUS NI L | C. b. iv | 1 84 5 | 1 1 - |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 40 CFR 158.340 Toxicology D 870.1100 | Acute oral toxicity | 42918628; 43235401 43279706 | BASF | OLD | |
| 870.1200 | Acute dermal toxicity | 42918629 | BASF | OLD | |
| 870.1200 | Acute dermal toxicity | 43235402 | BASF | OLD | |
| 870.1300 | Acute inhalation toxicity | 42918631 | BASF | OLD | |
| 870.2400 | Primary eye irritation | 42918632 | BASF | OLD | |
| 870.2500 | Primary dermal irritation | 42918630 | BASF | OLD | |
| 870.2600 | Dermal sensitization | 42918634 | BASF | OLD | |
| 870.6100 | Acute delayed neurotoxicity | 42918635 | BASF | OLD | |
| 870.6100 | Acute delayed neurotoxicity | 43559501 | BASF | OLD | |
| 870.3100 | 90-day oral toxicity - rodent | 42918643 | BASF | OLD | |
| 870.3150 | 90-day oral toxicity - nonrodent | 42918642 | BASF | OLD | |
| 870.3200 | 21-day dermal toxicity | 42918644 | BASF | OLD | |
| 870.3250 | 90-day dermal toxicity | DATA GAP | BASF | GAP | *See below |
| 870.6100 | 90-day neurotoxicity – mammal | 43291703 | BASF | OLD | |
| 81-8 | Neurotoxicity to Rats by Acute Oral Administration | 44431801 | BASF | PAY | |
| Signature | The second | | Name and Title Jean-Pascal Marc Corporate Product Innovation Direct | or | Date August 23, 2011 |

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| | DA | TA MATRIX | | | |
|--|---|--|---|---------------------------------------|----------------------------|
| Date August 23, 2011 | | | | | Page 4 of 6 |
| Applicant's/Registrant's Name & A | ddress | | Product: Fipronil Technical | | |
| Virbae SA | | | | | } |
| 1ere avenue 2065 M - LID F-06516 Carros, France | | | | | |
| Ingredient: Fipronil | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 40 CFR 158.340 Toxicology D | ata Requirements (Continued) | | | | |
| 84-2 | Structural chromosomal aberration | 42918680 | BASF | OLD | |
| 84-2 | Structural chromosomal aberration | 42918653 | BASF | OLD | - |
| 84-2 | Other genotoxic effects | 42918651;42918653 43501703 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42918655 | BASF | OLD | |
| 85-1/870,7485 | General metabolism | 43253701 | BASF | PAY | |
| 85-1/870.7485 | General metabolism | 43737308 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42918654 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42977904 | BASF | OLD | - |
| 85-1/870.7485 | General metabolism | 43253701 | BASF | OLD | Ţ |
| 85-2/870.7600 | Dermal penetration | 43737308 | BASF | PAY | |
| 85-7/870.7600 | Immunotoxicity | DATA GAP | | GAP | *See below |
| 40 CFR 158.490 Wildlife and | Aquatic Organisms Data Requirements | | | OLD | <u> </u> |
| 71-1/850.2100 | Avian oral LD 50 - mallard or bobwlite | 42918617 42918616 | BASF | OLD | |
| 72-1/850.1075 | Freshwater fish LC 50 – rainbow or blnegill | 42918624;42918673; 42918674;42977902 43279703;43291718 | BASF | OLD OLD | |
| Signature | | | Name and Title Jean-Pascal Mare Corporate Product Impovation Director | · · · · · · · · · · · · · · · · · · · | Date August 23, 2011 |

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| | | DATA MATRIX | | | |
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| Date: August 23, 2011 | | EPA Reg. No./File Symbol 87825-R | | Page 5 of 6 | |
| Virhae SA lere avenue 2065 M - LID F-06516 Carros, France | | | Product: Fipronii Technical | | |
| Ingredient: Fipronil | | | | | |
| Guideline Reference Number | Guideline Study Name | MRtD Number | Submitter | Status | Note |
| 83-1/870.4100 | Chronic feeding - rodent | 42918648 | BASF | OLD | |
| 83-1/870.4100 | Chronie feeding - nonrodent | 42918645 | BASF | OLD | |
| 83-1/870.4100 | Chronic feeding - nonrodent | 43402802 | BASF | PAY | |
| 83-2/870.4200 | Oncogenicity - mouse | 42918649 | BASF | OLD | |
| 83-2/870.4200 | Oncogentality – mouse | 43501702 | BASF | PAY | |
| 83-2/870.4200 | Oncogenicity – rat | 42918648 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rabbit | 42918646 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rat | 42977903 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rat | 44275001 | BASF | PAY | |
| 83-6/870.6300 | Developmental neurotoxicity | 44039002 | BASF | PAY | |
| 83-4/870.3800 | Reproduction | 42918647 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 42918652 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 42918679 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291716 | BASF | OLD | |
| 84-2/870,5100 | Gene mutation | 43291717 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291721 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291722 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43401102 | BASF | OLD | |
| Signature | 1 Augustin | | Name and 'fitie Jean-Pascal Marc Corporale Product Innovation I | Director | Date Angust 23, 2011 |

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| Date: Angust 23, 2011 | | | EPA Reg. No./file Symbol 87825-R | Page 6 nf 6 | |
| Applicant's/Registram's Name & Addr | ess | | Product: Fipronil Technical | | |
| Virbae SA | | | | | |
| lete avenue 2065 M - LID | | | | | |
| f-06516 Carros, France Ingredient: Fipronil | | | | | <u> </u> |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Cinton | Note |
| 72-2/850.1010 | | | | Status | Note |
| 72-2/830.1010 | Acute LC 50 freshwater invertebrates (Daphnia magna) | 42918625 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daphnia magna) | 42918669 | BASF | OLD | |
| | Acute LC 50 freshwaler invertebrates (Daphnia magna) | 42918671 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daphnia magna) | 43291719 | BASF | QLD | |
| 835.2110 | Hydrolysis | 42977905 | BASF | OLD | |
| 40 CFR 158.390 Reentry Protection Data Requirements | | | | | |
| 133-3 | Dermal exposure - Fipronil | 44433302 | Merial | PAY | |
| 133-4 | Inhalation exposure - Fipronil | 44433302 | Merial | PAY | |
| 132-1 | Distodgeable residue dissipation - Fipronil | 44531203 | Merial | PAY | |
| N/A | Dermal and inhalation exposure of commercial pet groomers (Spot) - Fipronil | 44433303 | Merial | PAY | |
| N/A | Analytical method for exposure studies - Fipronil | 44433308 | Merial | PAY | |
| Signature |] h | | Name and Title Jean-Pascal Marc Corporate Product Innovation Director | | August 23, 2011 |

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^{*} Pursuant to 40 CFR t52.96 (c), Virbae hereby certifies that Virbae has no basis to believe that this requirement is not a data gap and, further, that Virbae has sent by certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbae will update the Agency as to the information, if any, Virbae receives in response to this "lata gap" letter.

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| | DA | ATA MATRIX | | | |
|---|--|--------------------|---|--------|-----------------------------|
| Date: December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | Page 1 of 9 |
| Applicant's/Registrant's Name & A | ddress | | Product: | | |
| Virbae AH, Inc. | | | | | |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | R DOGS | 1 |
| Fort Worth TX 76161 | | | | | |
| Ingredient: Fipronil, Pyriproxyfen Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Product Chemistry Test Guide | | I MINITO IMINITOGI | Sdommer | Status | NOIC |
| 830.1550 | Product Identity and Composition | New Submission | Virbac AH, Inc. | OWN | |
| 830.1600 | Description of Materials Used | New Submission | Virbac AH, Inc. | OWN | |
| 830.1620 | Description of Production Process | New Submission | Virbac AH, Inc. | OWN | <u></u> |
| 830.1650 | Description of Formulation Process | New Submission | Virbac AH, Inc. | OWN | |
| 830.1670 | Description of Formation of Impurities | New Submission | Virbac AH, Inc. | OWN | |
| 830.1700 | 5-Batch Analysis | New Submission | Virbac Ald, Inc. | OWN | |
| 830.1750 | Certified Limits | New Submission | Virbac AH, Inc. | OWN | |
| 830.1800 | Analytical Method | New Submission | Virbac AH, Inc. | OWN | |
| 830.6302 | Color | New Submission | Virbac AH, Inc. | OWN | |
| 830,6303 | Physical State | New Submission | Virbac AH, Inc. | OWN | |
| 830.6304 | Odor | New Submission | Virbac AH, Inc. | OWN | |
| 830.6313 | Metal Stability | | Virbac AH, Inc. | NR | |
| 830.6314 | Oxidation/reduction | New Submission | Virbac AH, Inc. | OWN | |
| 830.6315 | Flanmability | New Submission | Virbac AH, Inc. | OWN | |
| 830.6316 | Explodability | | Virbac AH, lnc. | NR | |
| 830.6317 | Storage stability | To be conducted | Virbac AH, Inc. | OWN | |
| Signature Leavy Kache | | | Name and Title Craig Parks Vice President, Research & Development | | Date Decembe 20, 2011 |
| • | | | | | 1 |

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| | DA | TA MATRIX | • | | |
|---|--|------------------|---|--------|------------------------------|
| Date December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | Page 2 of 9 |
| Applicant's/Registrant's Name & Address Virbac All, Inc | | | Product: | | |
| PO Box 162059 Fort Worth TX 76161 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | R DOGS | |
| Ingredient: Fipronil, Pyriproxyten | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 830.7100 | Viscosity | New Submission | Virbae AH, Inc. | OWN | |
| 830.6319 | Miscibility | | Virbac AH, Inc. | NR | |
| 830.6320 | Corrosion characteristics | To be conducted | Virbac AH, Inc. | OWN | |
| 830.6321 | Dielectric breakdown voltage | | Virbac AH, Inc. | NR | |
| 830.7000 | pH | New Submission | Virbae AH, Inc. | OWN | |
| 830,7300 | Density, bulk density, or specific gravity | New Subntission | Virbac AH, Inc. | OWN | |
| 830.7320 | Particle Size distribution | | Virbae AH, Inc. | NR | |
| 40 CFR 158.340 Toxicology D | ala Requirements | <u> </u> | | | |
| 870.1100 | Acute oral toxicity | New Submission | Virbac AH, Inc. | OWN | |
| 870.1200 | Acute dermal toxicity | New Submission | Virbac AH, luc. | OWN | |
| 870.1300 | Acute initalation toxicity | Waiver requested | Virbac AH, Inc. | | |
| 870.2400 | Primary eye irritation | New Submission | Virbac AH, Inc. | OWN | |
| 870.2500 | Primary dermal irritation | New Submission | Virbac AH, Inc. | OWN | |
| 870.2600 | Dermal sensitization | New Submission | Virbac AH, Inc. | OWN | |
| Signature Laig kah | | | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 |

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| | nd the form to this address. | TO A TO A TATA SEPTEMBER | | | |
|--------------------------------------|------------------------------|--------------------------|---|----------|-------------|
| | | DATA MATRIX | | ******* | Page 3 of 9 |
| Date: December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | |
| Applicant's/Registrant's Name & A | ddress | Product: | Product: | | |
| Virbac AH, Inc | | | DECIDE OF BLUE PODICAL COLUMNA P | An DAAGE | |
| PO Box 162059 Fort Worth TX 76161 | | | EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS | | |
| Ingredient: Fipronil, Pyriproxyfen | | | | | <u> </u> |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Efficacy and Safety Data | | | | | |
| 870.7200 | Dog safety | 43444905 | Merial | OLD | |
| 870.7200 | Dog safety | 43577711 | Merial | OLD | |
| 870.7200 | Dog safety | 43863802 | Merial | OLD | |
| 870,7200 | Dog safety | 43121110 | Merial | OLD | |
| 870.7200 | Dog safety | 43121111 | Merial | OLD | |
| 870.7200 | Dog safety | 45620507 | Merial | PAY | |
| 870.7200 | Dog safety | 43396408 | Ecto Development Corporation | OLD | |
| 870.7200 | Dog safety | 43612601 | Ecto Development Corporation | OLD | |
| 870.7200 | Dog safety | 44900902 | Virbac AH, Inc. | OWN | |
| 870.7200 | Dog safety | 44900903 | Virbac AH, Inc. | OWN | |
| 870.7200 | Dog safety | 42178309 | Sumitomo Chemical Company, Ltd. | OLD | |
| 870.7200 | Dog safety | New submission | Virbac AH, Inc. | OWN | |
| 810.3300 | Efficacy | 43121114 | Merial | OLD | |
| 810.3300 | Efficacy | 43121115 | Merial | OLD | |
| 810.3300 | Efficacy | 43121116 | Merial | OLD | |
| 810.3300 | Efficacy | 43121117 | Merial | OLD | |
| 810.3300 | Efficacy | 43121118 | Merial | OLD | |
| 810.3300 | Efficacy | 43121119 | Merial | OLD | |
| 810.3300 | Efficacy | 43121120 | Merial | OLD | |
| Signature | | | Name and Title | | Date |
| Cany take | | | Craig Parks | | December |
| cay man | | | Vice President, Research & Development | | 20,2011 |



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| | | DATA MATRIX | | | |
|------------------------------------|----------------------|--|--|--------|-----------------------------|
| Date: December 20, 2011 | | EPA Reg. No./File Symbol 2382-TBA | Page 4 of 9 | | |
| Applicant's/Registrant's Name & A | ddress | | Product: | | |
| Virbac Alt, Inc | | | | | |
| PO Box 162059 Fort Worth TX 76161 | | | EFFIPRO® PLUS TOPICAL SOLUTION | | |
| Ingredient: Fipronil, Pyriproxyfen | | | <u> </u> | | |
| Guideline Rescrence Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Efficacy and Safety Data | | | | | |
| | | | | | |
| 810.3300 | Efficacy | 43121121 | Merial | OLD | |
| 810,3300 | Efficacy | 43121122 | Merial | OLD | |
| 810,3300 | Efficacy | 43444901 | Merial | OLD | |
| 810.3300 | Efficacy | 43577701 | Merial | OLD | |
| 810.3300 | Efficacy | 43577712 | Merial | OLD | |
| 810.3300 | Efficacy | 43577713 | Merial | OLD | |
| 810.3300 | Efficacy | 43951701 | Merial | OLD | |
| 810.3300 | Efficacy | 44088901 | Merial | OLD | |
| 810.3300 | Efficacy | 46006002 | Wellmark International | PUBL | |
| 810.3300 | Efficacy | 44900904 | Virbac AH, Inc. | OWN | |
| 810.3300 | Efficacy | 45020601 | Virbac AH, Inc. | OWN | |
| 810.3300 | Efficacy | Pending; submitted with Effipro Plus Cat Application | | OWN | |
| 810.3300 | Efficacy | New subnitssion | | OWN | |
| Signature Long Lake | | | Nnme and Title Craig Parks Vice President, Research & Developm | cni | Date Decembe 20, 2011 |

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| | | DATA MATRIX | · · · · · · · · · · · · · · · · · · · | | |
|--|----------------------|----------------------------------|--|--------|------------------------------|
| Date December 20, 2011 | | EPA Reg. No./File Syntbol 2382-T | Page 5 of 9 | | |
| Applicant's/Registrant's Name & Address Virbae AH, Inc PO Box 162059 Fort Worth TX 76161 | | | Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS | | |
| Ingredient: Fipronil, Pyriproxyfen | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Suhmiter | Stalus | Note |
| 810,3300 | Efficacy | 44942011 | Merial | PAY | |
| 810.3300 | Efficacy | 44942106 | Merial | PAY | |
| 81 0.3300 | Efficacy | 45612701 | Merial | PAY | |
| 810.3300 | Efficacy | 45618501 | Merial | PAY | |
| 810.3300 | Efficacy | 45620501 | Merial | PAY | |
| 810.3300 | Efficacy | 45620502 | Merial | PAY | |
| 810.3300 | Efficacy | 45620503 | Merial | PAY | |
| 810.3300 | Efficacy | 45620504 | Merial | PAY | |
| 810.3300 | Efficacy | 45620505 | Merial | PAY | |
| 810,3300 | Efficacy | 45620506 | Merial | PAY | |
| 810.3300 | Efficacy | 45628101 | Merial . | PAY | |
| 810,3300 | Efficacy | 45628102 | Merial . | PAY | |
| 810.3300 | Efficacy | 45628103 | Merial | PAY | |
| 810.3300 | Efficacy | 45628104 | Merial | PAY | , |
| 810.3300 | Efficacy | 45628105 | Merial | PAY | |
| 810.3300 | Efficacy | 45628201 | Merial | PAY | |
| 810,3300 | Efficacy | 45866901 | Merial | PAY | |
| 810.3300 | Efficacy | 45866902 | Merial | PAY | |
| 810.3300 | Efficacy | 46019201 | Merial | PAY | |
| 810.3300 | Efficacy | 46019202 | Merial | PAY | |
| Signature Lang Kah | | | Name and Title Craig Parks Vice President, Research & Develo | ppnent | Date December 20, 2011 |

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| | DAT | A MATRIX | | | | |
|---|--|-----------------------------------|---|--------|------------------------------|--|
| Date: December 20 | , 2011 | EPA Reg. No./File Symbol 2382-TBA | Page 6 of 9 | | | |
| | ni's Name & Address | Product: | | | | |
| Virbae AH, Inc | | | | | į | |
| PO Box 162059 | • | | EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS | | | |
| Fort Worth TX 7616 | | | | | <u> </u> | |
| Ingredient: Fipronil, Guideline | Guideline Study Nante | MRID Number | Submitter | Status | Note | |
| Reference Number | Culdeline Study Name | MAID Namber | Subhinter | Status | Note | |
| Child Resistant P | ackaging | | | | | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Child-Resistant Effectiveness | 48095221 | Virbac AH, Inc. | OWN | | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Child-Resistant Effectiveness | | Virbac AH, Inc. | OWN | | |
| 40 CFR 157 | | | Virbac AH, Inc. | OWN | | |
| 40 CFR 157 Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Senior-Use Effectiveness 48095 | | 48095224 | Virbac AH, Inc. | OWN | | |
| 40 CFR 157 | | | Virbac AH, lnc. | OWN | | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Schior-Use Effectiveness | 48095226 | Virbac AH, Inc. | OWN | | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68ml water, 1 applicator tube test for Child-Resistant Effectiveness | Virbac AH, Inc. | OWN | | | |
| Signature Leany land | | | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 | |

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| Date: December 16, | 2011 | EPA Reg. No./File Symhol 2382-TBA | Page 7 of 9 | | |
| | nt's Name & Address | | Product: | | |
| Virbae AH, Inc | | | | | Į |
| PO Box 162059 | : | | EFFIPRO® PLUS TOPICAL SOLUTION FO | R DOGS | |
| Port Worth TX 7616 | | | <u> </u> | | |
| Ingredient: Fipronil, | | | | | |
| Guideline Reference Number | Guidefine Study Name | MRID Number | Submitter | Status | Note |
| 40 CFR 157 | Evaluation of the 3 tnl Applicator Tube with 2.68 ml water, 6 | 48095228 | Virbac AH, Inc. | OWN | ļ |
| 10 01 11 15 1 | applicators tube test for Child-Resistant Effectiveness | 10075220 | Thous ran, me. | 10"" | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 | 48095229 | Virbae AH, Inc. | OWN | |
| · | applicators tube test for Child-Resistant Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, I | 48095230 | Virbac AH, Inc. | OWN | |
| | applicator tube test for Senior-Use Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 | 48095231 | Virbac AH, Inc. | OWN | |
| | applicators tube test for Senior-Use Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 | 48095232 | Virbac AH, Inc. | OWN | |
| | applicators tube test for Senior-Use Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 1 | 48095233 | Virbac AH, Inc. | OWN | |
| | applicator tube test for Child-Resistant Effectiveness | | | | ĺ |
| 40 CFR 157 | Evaluation of the 6 tnl Applicator Tube with 4.02 ml water, 6 | 48095234 | Virbac AH, Inc. | OWN | |
| | applicators tube test for Child-Resistant Effectiveness | | Í | 1 | |
| 40 CFR 157 | Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 | 48095235 | Virbac AH, Inc. | OWN | |
| | applicators tube test for Child-Resistant Effectiveness | | | <u> </u> | |
| Signature | | | Name and Title | | Date |
| 1.11 | | | Craig Parks | | December |
| Crasy Kake | | | Vice President, Research & Development | | 20, 2011 |
| | Shahariy and Paray Varriana Amillahla, Subait and Paray Interior | | | | |

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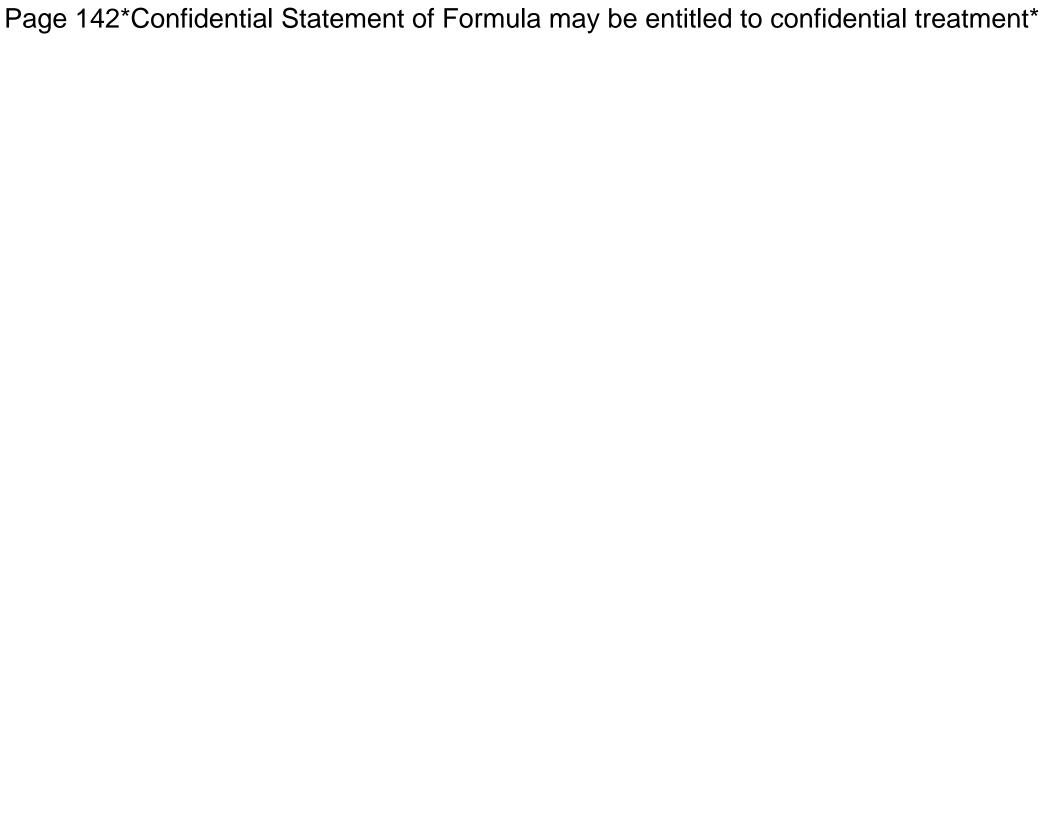
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| Date: December 20, | | EPA Reg. No./File Symbol 2382-TBA | | Page 8 of 9 | |
| | nt's Name & Address | Product: | | | |
| Virbae Al-l, luc | | | | |] |
| PO Box 162059 Fort Worth TX 7616 | 1 | | EFFIPRO® PLUS TOPICAL SOLUTION F | OR DOGS | |
| Ingredient: Fipronil, 1 | | | | ···· | L |
| Guideline | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Reference Number | Olisacinio osagy rante | Wild Milloca | Dublifice | Status | 14010 |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Child-Resislant Effectiveness | 48410001 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48410002 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Child-Resistant Effectiveness | 48410003 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1 ml applicator tube with 0.67 ml water, 6 applicator tube test for Scnior-Use Effectiveness | 48410004 | Virbac AH, Iuc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Child-Resistant Effectiveness | 48410005 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 36 applicator tube test for Senior-Use Effectiveness | 48410006 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410007 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 inl water, 3 applicator tube test for Senior-Use Effectiveness | 48410008 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 1.34 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410009 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3rd applicator tube with 1.34 ml water, 3 applicator tube test for Senior-Use Effectiveness | 48410010 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410011 | Virbac AH, Inc. | OWN | |
| Signature Craig Rah | | | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 |

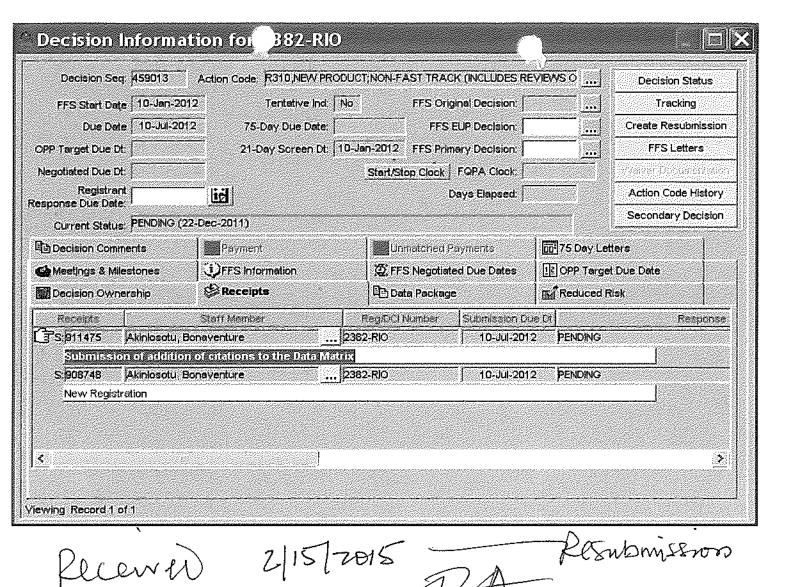
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| Date December 20, 2 | 2011 | EPA Reg. No./File Symbol 2382-TBA | Page 9 of 9 | | |
| | nt's Nanie & Address | | Product: | | |
| Virbac AH, Inc | | | | | |
| PO Box 162059 | , | | EFFIPRO® PLUS TOPICAL SOLUTION | FOR DOGS | i |
| Fort Worth TX 7616 Ingredient: Pipronil, | | | | | |
| Guideline | Guideline Study Name | MRID Number | Subnitter | Status | Note |
| Reference Number | | | | | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 nd water, 3 applicator tube test for Schior-Use Effectiveness | 48410012 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410013 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Senior-Use Effectiveness | 48410014 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48410015 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 36 applicator tube test for Senior-Use Effectiveness | 48410016 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6ml applicator tube with 4.02 ml water, 6 applicator tube test for Senior-Use Effectiveness | 48410017 | Virbac AH, Inc. | OWN | |
| Signature | | | Name and Title | | Date December |
| Craig Rah | | | Craig Parks Vice President, Research & Development | | 20, 2011 |





| Decision Seq: | 459013 <i>J</i> | Action Code: R310,N | IEW PRODUCT | I;NON-FAST TRAC | K (INCLUDES R | EVIEWS | Decision Status |
|----------------------------------|-----------------|---|---------------|----------------------------|-------------------------------|------------------------|--------------------------|
| FFS Start Date | 10-Jan-2012 | Tentati | ive Ind No | FFS Origi | nal Decision: | **** | Tracking |
| Due Date | 10-Jul-2012 | 75-Day Due | e Date | FFSE | UP Decision: | | Create Resubmission |
| IPP Target Due Dt | | 21-Day Scrr | een Ot 10-Jan | n-2012 FFS Prime | nry Decision: | 444 | FFS Letters |
| Negotiated Due Dt. | | - | | Start/Stop Clock | FOPA Clock | | VValver (22) unientelion |
| Registrant Esponse Due Date | | _ [6] | | Di | ays Elapsed: | | Action Code History |
| Current Status: | PENDING (22-) | *************************************** | - | | | | Secondary Decision |
| Decision Comments | | | | Unmaiched Paymenta | | 75 Day Letters | |
| Meetings & Milestones | | ①FFS Information | | ② FFS Negotiated Due Dates | | IP OPP Target Due Date | |
| Decision Ownership | | Receipts | | Bi∋ Data Package | | Reduced Risk | |
| Recepts डिड 908748 A | kiniosotu, Bon | Staff Member naventure | P [2382 | egCCI suraser P-RIO | Subression Dis 10-Jul-2012 | | Response |
| New Registrat | | | | | | | |

Received 1/31/2012 BA

Fee for Service



| This package includes the following | for Division |
|--|--|
| New Registration Amendment | ○ AD ○ BPPD • RD |
| Studies? □ Fee Waiver?□ volpay % Reduction: | Risk Mgr. 10 |
| Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date: | 908748 2382-RIO 12/20/2011 |
| This item is NOT subject t | o FFS action. |
| Action Code: Requested: Granted: Amount Due: \$ 4807.00 | Parent/Child Decisions: |
| Inert Cleared for Intended Use Reviewer: | Uncleared Inert in Product Date: 12/4/11 |

PRIA 2 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only) 3/23/09

| | | 3/23/07 | | | | | |
|----------------------------------|------|---------|-------|--------|---------|-----------|-------|
| 21 Day Screen Start Date: | 12-2 | 0-11 | | | _ | | |
| Experts In-Processing Signature: | MF | HARRING | 704 I | Date_/ | 11-22-1 | Fee Paid: | Yes 1 |
| Division management contacted on | | | Yes | | Date | | • |

| Saagaa Geraesa ka | Reg. Number: 2382-RIO EPA Receipt Date: | 1 6. | -20- | / | 8.43 (8.2) (8.1) | |
|-------------------|---|---------------|---------|---------|------------------|------|
| | Items for Review | | | Yes | No | N/A* |
| 1 | Application Form (EPA Form 8570-1)(link to form) signed including package type | X | | | | |
| 2 | Confidential Statement of Formula all boxes completed, fo dated (EPA Form 8570-4) (Link to form) | rm signed, | and | X | | |
| 2 | a) All inerts (link to http://www.epa.gov/opprd001/inerts/), | yes | no | | | |
| | including fragrances, approved for the proposed uses (s Footnote A) | X | | - | | |
| 3 | Certification with Respect to Citation of Data (EPA Form form) completed and signed (N/A if 100% repack) | 8570-34) (1 | ink to | × | | |
| | Certificate and data matrix consistent | | | X | | |
| | If applicant is relying on data that are compensable, is the off to pay statement included. (see Footnote B) | er yes | no | - | | - |
| · | If applicable, is there a letter of Authorization for exclusive u | | | | | |
| 4 | Formulator's Exemption Statement (EPA Form 8570-27) (completed and signed (N/A if source is unregistered or applicatechnical) | | | X | | |
| | Data Matrix (EPA Form 8570-35) (Link to form) both interropies (PR 98-5) (Link to PR 98-5) completed and signed (Na repack) | | rnal | X | | |
| 5 | a) Selective Method (Fee category experts use) | yes | no | | | |
| | b) Cite-All (Fee category experts use) | | | | | |
| | c) Applicant owns all data (Fee category experts use) | | | | | |
| 6 | 5 Copies of Label (link to http://www.epa.gov/oppfead1/la (Electronic labels on CD are encouraged and guidance is a http://www.epa.gov/pesticides/regulating/registering/submissions/in) | available)(| link to | χ | | |

| 7 | Is the data package consistent with PR Notice 86-5 (link to PRN 86-5) | X | |
|----|--|---|---|
| 8 | Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm) | / | X |
| 9 | If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html) | | X |
| 10 | Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C. a) List study (or studies) not included with application | | |

Comments:

A Inen's approved for non-food use

Jacket Pass 86-5 Pass

PG/AB

MRIO 486969

* N/A - Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses even if a product is currently registered by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to

http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
 number, providing documentation that the inert has been approved, or
 removing the unapproved inert from the CSF or replacing it with one that is
 approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



Bonaventure Akinlosoto
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

February 6, 2012.

2382-R1O; Effipro Plus for Dog Revised Data Matrix.

Dear Bonaventure,

We received your email earlier today requesting the addition of citations to the Data Matrix for the pending product listed above to include MRID numbers for studies supporting SAUE testing with the 4.02 ml fill level tube and both the 1 and 36 tube count packages.

Please find a Data Matrix revised accordingly and dated February 6, 2012.

Note that we have emailed courtesy copies of these same documents to you in pdf format.

Best Wishes,

Craig

Craig Parks, DVM

VP Research and Development

Form Approved OMB No. 2070-0060

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|-------------------------------------|--|-----------------|--|--------|--------------------|
| Date: February 6, 2012 | | | EPA Reg. No. File Symbol 2382-RIO | | |
| Applicant's/Registrant's Name & / | Address | | Product: | | |
| Virbae AH, Inc. | | | | | |
| PO Box 162059 Fon Worth TX 76161 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | R DOGS | |
| lugrediem: Fipronil, Pyriproxyfeu | <u> </u> | | | | |
| Guidelioe Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Product Chemistry Test Guid | | | | | |
| 830.1550 | Product Identity and Composition | New Submission | Virbac AH, Inc. | OWN | |
| 830.1600 | Description of Materials Used | New Submission | Virbae AH, Inc. | OWN | |
| 830.1620 | Description of Production Process | New Submission | Virbac AH, Inc. | OWN | |
| 830,1650 | Description of Enropulation Process | New Submission | Virbae AH, Inc. | OWN | |
| 830.1670 | Description of Formation of Impurities | New Submission | Virbac AH, Inc. | OWN | |
| 830.1700 | 5-Batch Analysis | New Submission | Virbac AH, Inc. | OWN | |
| 830.1750 | Certified Limits | New Submission | Virbac AH, Inc. | OWN | |
| 830.1800 | Analytical Method | New Submission | Virbac AH, Inc. | OWN | |
| 830.6302 | Color | New Submission | Virbae AH, Inc. | OWN | |
| 830.6303 | Physical State | New Submission | Virbac AH, Inc. | OWN | |
| 830.6304 | Odnr | New Submission | Virbac AH, Inc. | OWN | |
| 830.6313 | Metal Stability | | Virbae AH, Inc. | NR | |
| 830.6314 | Oxidation/reduction | New Submission | Virbac AH, Inc. | OW'N | |
| 830.6315 | Flammability | New Submission | Virbac AH, Inc. | OWN | |
| 830.6316 | Explodability | | Virbac AH, Inc. | NR | |
| 830.6317 | Storage stability | To be conducted | Virbac AH, Inc. | OWN | |
| Signature | | | Name and Title | | Date |
| Ceang hahr | | | Craig Parks Vice President, Research & Development | | Feliriiary 6, 2012 |
| (cay m | | | | | |

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| | D.A | ATA MATRIX | | | |
| Date February 6, 2012 | | | El'A Reg. Np./File Symbol 2382-RIO | | Page 2 of 9 |
| Applicant's/Registrant's Name & / | Address | | Product: | | |
| Virbae AH, Inc | | | GININA A SERVICIO DE LA CALLERIA DEL CALLERIA DE LA CALLERIA DEL CALLERIA DE LA C | 20.0000 | |
| PO Box 162059 Fort Worth TX 76161 | | | EFFIPRO* PLUS TOPICAL SOLUTION FO | OK DOGS | |
| Ingredient: Fipronil, Pyriproxyfea | | · | | | |
| Guideline Reference Number | Guideline Stody Name | MRID Number | Suhmitter | Status | Note |
| 830.7100 | Viscosity | New Submission | Virbac AH, Inc. | OWN | |
| 830.6319 | Miscibility | | Virbac AH, Inc. | NR | |
| 830.6320 | Corrosion characteristics | To be conducted | Virbae AH, Inc. | OWN | |
| 830,6321 | Dielectrie breaktlown voltage | | Virbac AH, Inc. | NR | |
| 830,7000 | pH | New Submission | Virbac AH, Inc. | OWN | |
| 830.7300 | Density, bulk density, or specific gravity | New Stibmission | Virbac AH, Inc. | OWN | |
| 830,7320 | Particle Size distribution | | Vîrbac AH, Inc. | NR | |
| 40 CFR 158.340 Toxicology D | ata Requirements | | | | |
| 870.1100 | Acute oral toxicity | New Submission | Virbac AH, Inc. | OWN | |
| 870.1200 | Acute dermal toxicity | New Submission | Virbac AH, Inc. | OWN | |
| 870.1300 | Acute inhalation toxicity | Wniver requested | Virbae AH, Inc. | | |
| 870.2400 | Primary eye irritation | New Submission | Virbac AH, Inc. | OWN | |
| 870.2500 | Primary dermal irritation | New Submission | Virbac AH, Inc. | OWN | |
| 870.2600 | Dermul sensitization | New Submission | Virbac Alt, Inc. | OWN | |
| Signature | | | Name and Title | | Date |
| Craig Kah | | | Craig Parks Vice President, Research & Development | | February 6, 2012 |
| - / | | | | | |



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| Date: February 6, 2012 | | | EPA Reg. Nu/File Symbol 2382-RIO | | |
| Applicant's/Registrant's Name & Address | | | Product: | | |
| Virbae AH, Inc | | | EFFORD Off DUNIA FOR GALL GOLD WINGON E | 0D D000 | ļ |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | OR DOGS | |
| Fort Worth TX 76161 Ingredient: Fipronil, Pyriproxylen | | | | | .L., |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Efficacy and Safety Data | 3.000.000 | | | | |
| 870.7200 | Dog safety | 43444905 | Merial | OLD | · · · · · · · · · · · · · · · · · · · |
| 870.7200 | Dog safety | 43577711 | Merial | OLD | |
| 870.7200 | Dog safety | 43863802 | Merinl | OLD | |
| 870.7200 | Dog safety | 43121110 | Merial | OLD | |
| 870.7200 | Dog safety | 43121111 | Merial | OLD | |
| 370.7200 | Dog safety | 45620507 | Merial | PAY | |
| 370.7200 | Dog safety | 43396408 | Ecto Development Corporation | OLD | 1 |
| 370.7200 | Dog safety | 43612601 | Ecto Development Corporation | OLD | |
| 870.7200 | Dog safety | 44900902 | Virbac AH, Inc. | OWN | |
| 870.7200 | Dog safety | 44900903 | Virbae AH, Inc. | OWN | |
| 370.7200 | Dog safety | 42178309 | Sumitomo Chemical Company, Ltd. | OLD | |
| 870.7200 | Dog safety | New submission | Virbae AH, Inc. | OWN | |
| 810.3300 | Efficacy | 43121114 | Merial | OLD | |
| 310.3300 | Efficacy | 43121115 | Merial | GLO | |
| 310.3300 | Efficacy | 43121116 | Merial | OLD | |
| 810,3300 | Efficacy | 43121117 | Merial | OLD | |
| 810.3300 | Efficacy | 43121118 | Merial | OLD | |
| 810.3300 | Elficacy | 43121)19 | Merial | OLD | |
| 810.3300 | Efficacy | 43121120 | Merial | OLD | |
| Signature Leanj Bah | | | Name and Title Cruig Parks Vice President, Rescarch & Development | | Date February 6 2012 |

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| Date: Feliriary 6, 2012 | | | EPA Rag. Nn. File Symbol 2382-RIO | | Page 4 of 9 |
| Applicant's/Registrant's Name & A | ddress | | Product: | | |
| Virhae AH, Inc | | | | | |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUTION I | OR DOGS | |
| Port Worth TX 76161 | | | | | <u> </u> |
| Ingredient: Fipnmil, Pyriproxyfen Guideline Reference Number | Guideling Study Name | MRID Number | Submitter | Slalus | Note |
| Efficacy and Safety Data | Ourocine oracy (varie | WRCH2 MILLOCI | 5 STIDUTE STATE OF THE STATE OF | Status | INCIC |
| Ellicacy and Salety Data | | | | ···· | |
| 810,3300 | Efficacy | 43121121 | Merial | QLD | |
| 810.3300 | Efficacy | 43121122 | Merial | QLIQ | |
| 310.3300 | Efficacy | 43444901 | Merial | OLD | |
| 810.3300 | Efficacy | 43577701 | Merial | OLD | |
| 810.3300 | Efficacy | ₫3577712 | Merial | QLD | ··· |
| 810.3300 | Efficacy | 43577713 | Merint | ÖLD | |
| 810,3300 | Efficacy | 43951701 | Merial | OLD | |
| 810.3300 | Efficacy | 44088901 | Merial | OLD | |
| 810.3300 | Efficacy | 46006002 | Wellmark International | PUBL | |
| 810.3300 | Efficacy | 44900904 | Virbac AH, Inc. | OWN | |
| 810,3300 | Efficacy | 45020601 | Vîrbac AH, Inc. | OWN | |
| 810.3300 | Efficacy | Pending; submitted with Effipro Plus Cat Application | | OWN | |
| 810.3300 | Efficacy | New submission | | OWN | |
| Signature Long line | | | Nume and Title Craig Parks Vice President, Research & Development | | Date Fehrnary 6 2012 |

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|--|----------------------|-------------|--|--------|----------------------------|
| Dute February 6, 2012 Applicant's/Registrant's Name & Address Virbae AH, Inc PO Box 162059 Fort Worth TX 76161 | | | EPA Reg. Nn./File Symbol 2382-RIO Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS | | |
| | | | | | |
| Gnideline Reference Number | Guideline Study Name | MRID Number | Submiter | Status | Note |
| 810,3300 | Efficacy | 44942011 | Merial | PAY | |
| 810.3300 | Efficacy | 49992106 | Merial | PAY | |
| 810.3300 | Efficacy | 45612701 | Merial | PAY | |
| 810.3300 | Efficacy | 45618501 | Merial | PAY | |
| 810.3300 | Efficacy | 45620501 | Meriul | PAY | |
| 810.3300 | Efficacy | 45620502 | Merial | PAY | |
| 310.3300 | Efficacy | 95620503 | Merial | PAY | 1 |
| 310.3300 | Efficacy | 45620504 | Merial | PAY | |
| 310.3300 | Efficacy | 45620505 | Merial | PAY | |
| 810.3300 | Efficacy | 45620506 | Merial | PAY | |
| 310.3300 | Elficacy | 45628101 | Merial | РАҮ | |
| 810.3300 | Ellicacy | 45628102 | Merial | PAY | |
| 810.3300 | Efficacy | 45628103 | Merial | PAY | <u> </u> |
| 810.3300 | Efficacy | 45628104 | Merial | PAY | |
| 310.3300 | Efficacy | 45628105 | Merial | PAY | |
| 810.3300 | Efficacy | 45628201 | Merial | PAY | |
| 810.3300 | Efficacy | 45866901 | Merial | PAY | |
| 810.3300 | Efficacy | 45866902 | Merial | PAY | |
| 810.3300 | Efficacy | 46019201 | Merial | PAY | |
| 810.3300 | Efficacy | 46019202 | Merial | PAY | |
| Signature Leasy Kah | | | Name and Title Craig Parks Vice President, Research & Development | | Date February 6 2012 |

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| Applicant's/Registraot's Naore & Address | | | Product: | | |
| Virbae AH, Inc | | | 02 | | |
| PO Box 162059 | | | EFFIPRO* PLUS TOPICAL SOLUTION FO | OR DOGS | |
| Fort Worth TX 7616 | | | | | <u> </u> |
| Ingredient: Fipronil, Guideline | Pyriproxyten Guideline Study Name | MRID Number | Submitter | Status | Note |
| Reference Number | Guidence Stray Name | MICIES INHIBEE | Suffinidel | Status | NOIC |
| Child Resistant P | ackaging | | | | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Child-Resistant Effectiveness | 48095221 | Virhac AH, Iuc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Child-Resistant Effectiveness | 48095222 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Child-Resistant Effectiveness | 48095223 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48095224 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tuhe with 1.34 ml water, 6 applicators (the test for Senior-Use Effectiveness | 48095225 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ntl Applicator Tube with 1.34 ml water, 36 applicators tube (est for Senior-Use Effectiveness | 48095226 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68ml water, 1 applicator take test for Child-Resistant Effectiveness | 48095227 | Virbac AH, Inc. | OWN | |
| Signature Lain Lain | | | Name and Title Craig Parks Vice President, Research & Development | | Date Fehruary 6 2012 |

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| PO Box 162059 | | | EFFIPRO* PLUS TOPICAL SOLUTIO | N FOR DOGS | |
| Fort Worth TX 7616 | · · · · · · · · · · · · · · · · · · · | | | | <u> </u> |
| Ingredient: Fipronil, | | | | | |
| Guideline | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Reference Number | | | | | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 | 48095228 | Virbae AH, Inc. | OWN | |
| | applicators tube test for Child-Resistant Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 | 48095229 | Virbac AH, Inc. | OWN | |
| | applicators tube test for Child-Resistant Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 3 of Applicator Tube with 2.68 ml water, 1 | 48095230 | Virbac AH, Inc. | OWN | |
| | applicator lube test for Senior-Use Effectiveness | | | 1 |) |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 | 48095231 | Virbac AH, Inc. | OWN | |
| 40 Ott 157 | applicators tube test for Senior-Use Effectiveness | 10075257 | Thought the | 0 | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 | 48095232 | Virbac AH, Inc. | OWN | ļ |
| 40 CFK 157 | | 40073232 | Villac Act, inc. | OWN | |
| | applicators tube test for Senior-Use Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 1 | 48095233 | Virbae AH, Inc. | OWN | |
| | applicator tube test for Child-Resistant Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 6 | 48095234 | Virbac AH, Inc. | OWN | |
| | applicators tube test for Child-Resistant Effectiveness | | ŕ | | 1 |
| 40 CFR 157 | Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 | 48095235 | Virbac AH, Inc. | OWN | |
| | applicators tube lest for Child-Resistant Effectiveness | 1.000.0 | , mans , m, me. | | |
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|---------------------------------|---|---|--|--------|-----------------------------|
| Dite February 6, 20 | 12 | | EPA Reg. Nn./File Cymbol 2382-RIO | | |
| Virbac AH, Inc PO Box 162059 | nt's Name & Address | Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS | | | |
| Ingredient: Fipnonil, | | , | | | <u> </u> |
| Guideline Reference Number | Guideline Study Nanie | MRID Number | Suhmider | Siahis | Note |
| 40 CFR 157 | Evaluation of the 1ml applicator tabe with 0.67 ml water, 1 applicator tabe test for Child-Resistant Effectiveness | 48410001 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48410002 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 6 applicator tube test for Child-Resistant Effectiveness | 48410H03 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tibe with 0.67 ml water, 6 applicator tube test for Senior-Use Effectiveness | 48410004 | Virbac AH, Ibc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tabe with 0.67 ml water, 36 applicator tabe test for Child-Resistant Effectiveness | 48410005 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the fml applicator tube with 0.67 ml water, 36 applicator tube test for Senior-Use Effectiveness | 48410006 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml ovator, 3 applicator tube test for Child-Resistant Effectiveness | 48410007 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tabe with 0.67 ml water, 3 applicator tabe test for Senior-Use Effectiveness | 48410008 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3rd applicator tube with 4,34 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 484111109 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator take with 1.34 ml mater, 3 applicator take test for Senior-Use Effectiveness | 48410010 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tabe with 2.68 ml water, 3 applicator tabe test for Child-Resistant Effectiveness | 48410011 | Virbac AH, Inc. | OWN | |
| Signature Long Kach | | | Name and Title Craig Parks Vice President, Research & Developmer | ot. | Date February 6, 2012 |

Form Approved OMN Vo. 1970-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. WASHINGTON, D.C. 20460

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| | DAT | 'A MATRIX | er grand de la la la la la la la la la la la la la | | |
|-------------------------------|--|--------------|---|-------------|----------------------------|
| Date February 6, 20 | 12 | | EPA.Reg. No./Fil. Symbol 2382-RIO | Page 9 of 9 | |
| | pplicant's/Registrant's Name & Address | | Product: | | |
| Virbac AH, Inc | | | | | |
| PO Box 162059 | | | EFFIPRO [®] PLUS TOPICAL SOLUTION | FOR DOGS | |
| Fort Worth TX 7616 | | | | | |
| Ingredient: Fipmnil, | | 3 (D) (D) NI | Submitter | T Ct store | Note |
| Guideline Reference Number | Guideline Study Name | MRID Number | Subnutter | Status | Note |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Senior-Use Effectiveness | 48410012 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410013 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Senior-Use Effectiveness | 48410014 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48410015 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 36 applicator tube test for Senior-Use Effectiveness | 48410016 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6ml applicator tube with 4.02 ml water, 6 applicator tube test for Senior-Use Effectiveness | 48410017 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6ml applicator tube with 4,02 ml water, 1 applicator tube test for Schior-Use Effectiveness | 48095236 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6ml applicator tube with 4.02 ml water, 36 applicator tube test for Senior-Use Effectiveness | 48095238 | Virbac AH, Inc. | OWN | |
| Signature Leavy Kache | | | Name and Title Craig Parks Vice President, Research & Development | | Date February 6 2012 |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

December 27, 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

VIRBAC AH, INC. VIRBAC AH, INC. 13001 ST. CHARLES ROCK ROAD BRIDGETON, MO 63044

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 20-DEC-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

December 22, 2011

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP Decision Number: D-459013

EPA File Symbol or Registration Number: 2382-RIO

Product Name: EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS

EPA Receipt Date: 20-Dec-2011 EPA Company Number: 2382

Company Name: VIRBAC AH, INC.

CRAIG PARKS, MS, DVM VIRBAC AH, INC. P.O. BOX 162059 FORT WORTH, TX 76161

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT; NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMISTRY; ACUTE TOXICITY; PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division



December 20, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject:

12.

EFFIPRO® PLUS Topical Solution for Dogs (EPA File Symbol 2382-TBA):

New Product Application.

Dear Mr. Gebken,

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX 76137, (Company Number 2382)) is hereby submitting an application to register the spot-on pesticide product EFFIPRO® PLUS Topical Solution for Dogs.

This product contains the active ingredients fipronil and pyriproxifen and is intended to control fleas, ticks, mosquitoes, and other pests on dogs only.

Pyriproxyfen itself is registered alone and in combination with other active ingredients in numerous end use products for spot-on insect growth regulator use on dogs.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Offer to Pay letters are being sent to the submitters of data cited in Virbac's application that were originally submitted within the past 15 years.

Below is a list of the components included with this application:

Copy of PRIA Check for category R-310 (\$4807).

1. Cover Letter; 2. Transmittal Document; Application for Pesticide Form 8570-1; 3. Confidential Statement of Formula-2 Copies; 4. 5. Data Matrix Form 8570-4; (EUP and TGAI); Certification of Data Citation Form 8570-34: 6. Proposed Label - 5 copies; 7. 3 copies of bound PR 86-5 compliant study reports supporting registration; 8. 9. Waiver Request for Acute Inhalation Study (attached to Cover Letter); Letter of Self-certification of Child-Resistant Packaging: 10. Fonnulator's Exemption Form 8570-27; and 11.

Child-Resistant Packaging

EFFIPRO® PLUS Topical Solution for Dogs and will be marketed in single dose unit applicators in packages of 1, 3, 6, and 36. These single dose applicators for the 0.67 ml, 1.34 ml, 2.68 ml, and 4.02 ml dose sizes have been previously tested, and CRP certification has been accepted by EPA. All relevant test data supporting self-certification have been reviewed are and cited in the attached Data Matrix. A self-certification letter is also attached.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this product. Consequently, please find a copy of one previously submitted check in the amount of \$4807 to cover the PRIA fee.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

Craig Parks, MS, DVM

Craig tach

Vice President, Research & Development

Virbac Animal Health, Inc.

Attachments

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac, Inc. (EPA Company Number 2382) P.O. Box 162059 Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use pro namely EFFIPRO® PLUS Topical Solution for Dogs. Effipro® EFFIPRO® PLUS Topical Solution for Dogs contains the active ingredients Fipronil and Pyriproxyfen.

SUBMITTAL DATE:

December 20, 2011

| Volume | Study Title | MRID No. |
|--------|---|----------|
| 1 | Administrative Materials Effipro® Plus Topical Solution for Dogs | |
| | Group A Product Chemistry | |
| 2 | OPPTS 830.1550, 830.1750, 830.1600, 830.1620, 830.1650, 830.1670 EFFIPRO® PLUS Topical Solution for Dogs | 48696901 |
| | Group B Product Chemistry | |
| 3 | OPPTS 830.6302, 830.6303, 830.6304 Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)" | 48696902 |
| 4 | OPPTS 830.6314 Determination of Oxidation / Reduction (Chemical Incompatibility) | 48696903 |
| 5 | OPPTS 830.6315 Determination of the Physico-Chemical Property "Flash Point" | 48696904 |
| 6 | OPPTS 830.7000 Determination of the Physico-Chemical Property "pH" | 48696905 |
| 7 | OPPTS 830.7100 Determination of Physico-Chemical Property "Viscosity" | 48696906 |
| 8 | OPPTS 830.7300 Determination of the Physico-Chemical Property "Relative Density" | 48696907 |

| Volume | Study Title | MRID No. |
|---------|--|----------|
| 9 | OPPTS 830.1700, 830.1800 | |
| | Quantification of the Active Ingredients Fipronil and Pyriproxyfen | 48696908 |
| | in Five Batches by Validated Methods | |
| 10 | OPPTS 830.1800 | |
| • | Enforcement Analytical Method – Quantification of the Active | 48696909 |
| | Ingredients Fipronil and Pyriproxyfen | |
| | Acute Toxicity | |
| 11 | OPPTS 870. 1100 | 40000040 |
| | Acute Oral Toxicity Study in Rats - Up-and-Down-Procedure | 48696910 |
| 12 | OPPTS 870.1200 | A |
| | Acute Dermal Toxicity Study in Rats | 48696911 |
| 13 | OPPTS 870.2400 | 48696912 |
| | Acute Eye Irritation Study in Rabbits | 10030312 |
| 14 | OPPTS 870.2500 | 48696913 |
| | Acute Dermal Irritation Study in Rabbits | |
| 15 | OPPTS 870.2600 | 48696914 |
| <u></u> | Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test | 10000314 |
| | Product Performance | |
| 16 | OPPTS 810.3300 | |
| | Summary of Efficacy Data for EFFIPRO® PLUS Topical Solution | 48696915 |
| | for Dogs | |
| | Product Safety | |
| 1.5 | OPPIEC 070 7300 | |
| 17 | OPPTS 870.7200 | 4900co+= |
| l | Summary of Companion Animal Safety Data for EFFIPRO® | 48696916 |
| | PLUS Topical Solution for Dogs | |

| Ptease read instructions on revers | e before completing form | | | Form . | Approved, | OMB No. | 2070-0060 | , Approval expires 5-3 t-98 |
|---|---|--------------------------------------|----------------------------|---------------------|---------------------|--------------------------|-----------------------|--|
| | Unit | ed States | | | | tration | | OPP Identifier Number |
| ⊕EPA | Environmental | Protection A | gency | | 4 | ndment | | |
| | Washing | ton, DC 20460 | | | Other | - | - | |
| | | | esticide – Sec | tion | | | | |
| Company/Product Number Virbac AH, Inc./ 2382- TBA | | | 2. EPA Produc | ct Mana | | 3. | . Propose | d Classification |
| Company/Product (Name) EFFIPRO PLUS Topical Soluti | on for Dogo | | PM# | | | | X None | Restricted |
| 5. Name and Address of Appli Virbac AH, Inc P.O. Box 162059 Fort Worth, TX 76161 | cant (Include ZIP Code) | | 6. Expedited | Review uct is si | r. In acco | ordance v dentical in | with FIFR n compos | A Section 3(c)(3) sition and labeling |
| Check if this is a new add | dress | | Product Name | _ | · | | | |
| | | Sect | ion - II | | | | | |
| Amendment – Explain be | low | | | inted la | bels in re | sponse t | O | |
| Resubmission in respons | e to Agency letter dated | | Agency "Me Too | | | | | |
| Notification – Explain belo | ow | | X Other – | Explair | n below | | | |
| | | | | | | | | |
| Explanation: Use additional p Application for registration | | | | d lette | ·r | | | |
| | | | | | | | | |
| | | Sec | tion III | | | | | |
| Material This Product Will b | | | | | | | | |
| Child-Resistant Packaging X Yes | Unit Packaging X Yes | | ater Soluble Pack Yes | aging | | | Meta | f Container al tic, PETÉ |
| No | No | | K No | | | | Glas | |
| *Certification must be submitted | If "Yes" Unit Packaging wgt. 0.67ml, 1.34 ml, | | 'Yes" ickage wgt | | No. per containe | r | Pape Othe | er (Specify) |
| | 2.68 ml, 4.02 ml | | | | | | F1 (| |
| 3. Location of Net Contents Int | Container | 4. Size(s) Reta 1, 3, 6, 36 ml tu | | | [| X On L | .abel | I directions ompanying product |
| 6. Manner in Which Label is A | ffixed to Product | x Lithograpi | | | Other | | -aver aut | |
| | | Paper glu Stenciled | ed . | | | | | |
| | | | ion IV | | | | | |
| Contact Person (Complete i | tems directty below for id | | vidual to be conta | cted, if | | | | |
| Name Craig Parks, MS, DVM | | Title Vice Presid | dent o/ Research | hne | I | elephone 82-647-3 | • | dude Area Code) |
| ordig Farko, mo, Dviii | | Developm Virbac AH | ent, | -11.0 | | 02 0 11 0 | | |
| | Cei | rification | 41 | | I | | 6. E | Date Application |
| I certify that the statements I ha I acknowledge that any knowing both under applicable law | ve made on this form and | all atlaclinients th | | | | | | Received |
| both under applicable law 2. Signature | | 3. Title | | | | | | (Stamped) |
| Craig Rah | | | dent of Research a Inc. | and Dev | velopmer | nt, | | |
| 4. Typed Name | | 5, Date | | | | | | |

Craig Parks, MS, DVM
EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolcte.

White - EPA File Copy (Original) Yellow - Applicant Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460

| Paperwork Reduction Act Notice: The public reporting burden for this collection of informat and 0.25 hours per response for reregistration and special review activities, including time for comments regarding burden estimate or any other aspect of this collection of information, incl Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Averto this address. | reading the instruction luding suggestions for t | s and completing the necessary forms. Send reducing the burden to: Director, Collection | | | | | |
|--|---|--|--|--|--|--|--|
| Certification with Respect to C | Citation of Data | | | | | | |
| Applicant's/Registrant's Name, Address, and Telephone Number Virbac AH, tnc./ PO Box t62059 Fort Worth TX/ 682-647-3576 | | EPA Registration Number/File Symbol 2382-TBA | | | | | |
| Active Ingredient(s) and/or representative test compound(s) Fipronil, pyriproxyfen | | Dale 12/19/11 | | | | | |
| General Use Pattem(s) (list all those claimed for this product using 40 CFR Part t58) Indoor residential Product Name EFFIPRO PLUS Topicat Solution for Dogs | | | | | | | |
| NOTE: If your product is a 100% repackaging of another purchased EPA-registers submit this form. You must submit the Formulator's Exemption Statement (EPA Formulator's Exemption Statement) | | r all the same uses on your label, you do not need lo | | | | | |
| I am responding to a Data-Call-In Notice, and have included with this form a be used for this purpose). | list of companies se | nt offers of compensation (the Dala Matrix form should | | | | | |
| SECTION I: METHOD OF DATA SUPF | ORT (Check one m | elhod only) | | | | | |
| I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). | under lhe | g the selective method of support (or cite-all option selective method), and have included with this form a d list of data requirements (the Data Matrix form must be | | | | | |
| SECTION II: GENERAL | OFFER TO PAY | | | | | | |
| [Required if using the cite-all method or when using the cite-all option under the selection of the cite-all options of the cite-a | · | ` | | | | | |
| SECTION III: CERT | IFICATION | | | | | | |
| I certify that this application for registration, this form for reregistration, or the application for registration, the form for reregistration, or the Data-Call-In response. In indicated in Section I, this application is supported by all data in the Agency's fites that substantially similar product, or one or more of the ingredients in this product; and (2) requirements in effect on the date of approval of this application if the application sour uses. | n addition, if the cite-a it (1) concern the pro is a type of data that | all option or cite-all option under the selective method is perties or effects of this product or an identical or would be required to be submitted under the data | | | | | |
| I certify that for each exclusive use study cited in support of this registration the wrillen permission of the original data submitter to cite that sludy. | or reregistration, Iha | at I am the original dala submitter or thal I have obtained ¹ | | | | | |
| I certify that for each study cited in support of this registration or reregistration submitter; (b) I have obtained the permission of the original data submitter to use the compensation have expired for the study; (d) the study is in the public literature; or (e) offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c) amount and terms of compensation, if any, to be paid for the use of the study. | study in support of th Thave notified in writ | nis application; (c) alt periods of eligibility for ting the company that submitted the study and have | | | | | |
| I certify that in all instances where an offer of compensation is required, cop accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will evidence to the Agency upon request, I understand that the Agency may initiate action FIFRA. | be submitted to the A | Agency upon request. Should I fail to produce such | | | | | |
| t certify that the statements I have made on this form and all attachm knowingly false or misteading statement may be punishable by fine or impriso | | | | | | | |
| Signature Cray Rah | Dale t2/19/t1 | Typed or Printed Name and Title Craig Parks, VP of Research and Development | | | | | |

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Product ingredient source information may be entitled to confidential treatment

Form Approved. C.AB No. 2070-0060. Approval expires 5-31-98 United States **Environmental Protection Agency €EPA** Washington, DC 20460 Formulator's Exemption Statement (40 CFR 152.85) EPA File Symbol/Registration Number Applicant's Name and Address Virbac Animal Health 2382-TBA P. O. Box 162059 Product Name Ft. Worth, TX 76137 EFFIPRO PLUS TOPICAL SOLUTION FOR DOGS Date of Confidential Statement of Formula (EPA Form 8570-4) October 21, 2011 As an authorized representative of the applicant for registration of the product identified above, I certify that: (1) This product contains the following active ingredient(s):pyriproxifen (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled. (3) Indicate by checking (A) or (B) below which paragraph applies: (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1) OR (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF (4) The following active ingredients in this product qualify for the formulator's exemption Source Active Ingredient Product Name Registration Number Pyproxifeu

Name and Title

Vice President, Research & Development

EPA Formi 8570-27 (Rev. 8-95)

Signature Long tach

White - EPA copy Yellow - Applicant copy

Date

December 19, 2011



December 19, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Child Resistant Packaging Certification

EFFIPRO® PLUS Topical Solution for Dogs;

EPA Reg. No. 2382-NEW

Dear Mr. Gebken:

I certify that the packaging used for the following product meets the standards of 40 CFR 157.32, including the revised standards in 16 CFR 1700.15(b), when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995).

• EFFIPRO® PLUS Topical Solution for Dogs (EPA Reg. No. 2382-NEW).

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX, 76137; (Company Number 2382) is submitting this child resistant packaging certification to support the pending new product application filed on the above date for EFFIPRO® PLUS Topical Solution for Dogs (EPA Reg. No. 2382-NEW).

Should you have any questions about this letter, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

Craig Parks, MS, DVM

Vice President, Research & Development

Virbac Animal Health, Inc.

Waiver Request

Registrant: Virbac Animal Health, Inc. Acute Inhalation Study (OPPTS 830.1300). Effipro Plus Topical Solution for Dogs.

The Effipro® Plus Topical Solution for Dogs product is composed of 9.7% w/w of the active ingredient fipronil and 2.9 % w/w of the active ingredient pyriproxifen. This product is packaged in single use non-refillable applicators that are intended for one time only spot-on applications to dogs.

The potential human inhalation exposure to this product is expected to be neglible. Only very small amounts of product are applied per application, depending the weight of the animal. Based on packaging considerations described in the proposed product labeling, the maximum volume of Effipro[®] Plus Topical Solution for Dogs that can be administered at one time to a dog using the largest available applicator size is approximately 4.0 ml. This application volume represents the worst case because it is the dose that is recommended only for use on dogs weighing more than 89 pounds. Therefore, according to the proposed label, a great deal of anticipated product use will occur at much lower volumes on smaller dogs.

Furthermore, the measured vapor pressure of both of the active ingredients, fipronil and pyriproxifen, are extremely low (2.8 x 10⁻⁹ mm Hg at 25°C and 1.0 x 10⁻⁷ mm Hg at 25°C, respectively), indicating that both active ingredients are essentially non-volatile and are therefore not expected to vaporize from the skin of the treated animal following application. The active ingredients will therefore not be available for inhalation after application according to label directions. Finally, the method of applying the liquid product directly to the pet creates no particulates, aerosols, or other respirable matter. Therefore, based on the criteria provided by the Agency in 40 CFR 158.500, footnote 4 under the Toxicology Data Requirements, a waiver of the acute inhalation study for these products is appropriate.



End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI). Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO) (circle one)

| Guideline No. | Group A: Product Chemistry Data | EP Data Submitted | | MP Data Submitted | | TGAI | |
|------------------|--|----------------------|----|----------------------|----|------|----|
| | Study Title | Yes | No | Yes | No | Yes | No |
| 830,1550 | Product Identity & Composition | \perp | | | | | |
| 830,1600 | Description of materials used to produce the product | × | | | | | |
| 830,1650 | De s cription of formulation process | | _ | | | | |
| 830.1670 | Discussion on the formation of impurities | Ź | | | ; | | |
| 830.1700 | Preliminary analysis | × | | | | | |
| 830,1750 | Certified limits (158.345) | | | | | | |
| 830,1800 | Enforcement analytic a l method | | | | | | |

| Guideline No. | Group B: Product Chemistry Data Study | | ata nitted | MP D Subm | ata nitted | TGAI | | |
|------------------|--|----------|---------------|--------------|---------------|------|----------|---|
| | Title | Yes | No | Yes | No | Yes | No | |
| 830,6302 | Color | × | | | | | | |
| 830,6303 | Physical State | \ | | | | | | |
| 830,6304 | Odor | L× | _ | | | | | |
| 830.6313 | Stability to normal and elevated temperatures metal and m etal ions | | | | | | | |
| 830,6314 | Oxidation/Reduction (Chemical incompatibility) | × | | | | | | |
| 830.6315 | Flammability | | | | | | | |
| 830.6316 | Explodability | Ž | | | | | <u> </u> | |
| 830,6317 | Storage stability | X | | | | | | |
| 830.6319 | Miscibility | 7 | | | | | | |
| 830,6320 | Corrosion Characteristics | XI | _ | | | | | (|
| 830,6321 | Dielectric Breakdown Voltage | \perp | | | | | | |
| 830,7000 | pH | × | | | | | | |
| 830,7050 | UV/ Visible Absorption | | | | | | | |
| 830,7100 | Viscosity | \perp | | | | | | |
| 830,7200 | Melting Point | | | | | | | |
| 830,7220 | Boiling Point | | | | | | | |
| 830,7300 | Density | | | | | | | |
| 830.7370 | Dissociation Constant | | | | | | | 7 |
| 830,7550 | Partition Coefficient | | | | | Š | | |
| 830.7840 | Water Solubility | | | | | | | |
| 830.7950 | Vapor Pressure | | | | | | | 7 |

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

| Guideline | Acute toxicity (6 pack) | Data submit | ted | Ci | ted | |
|-----------|-------------------------|----------------|-----|-----|-----|--------------|
| No. | Study Title | Yes | No | Yes | No | |
| 870.1100 | Acute Oral (LD50) | <u> </u> | | | | |
| 870.1200 | Acute Dermal (LD50) | | | | | |
| 870.1300 | Acute Inhalation (LC50) | X | | | | wave Request |
| 870.2400 | Acute Eye Irritation | | | | | |
| 870.2500 | Acute Dermal Irritation | | | | | |
| 870.2600 | Dermal Sensitization | | | | | |

Efficacy - which guideline is used depends on the proposed label use

| Guideline No. | | | Data submitted | | ed | | |
|------------------|---|--------------|-------------------|-----|----|----------|--|
| | Study Title | Y e s | No | Yes | No | Comments | |
| 810.3100 | Soil Treatments for Imported Fire Ants | | | | | [- | |
| 810.3200 | Livestock, Poultry, Fur and Wool-8earing Animal Treatments | | | | | | |
| 810.3300 | Treatments to Control Pests of Humans and Pets | | | | | | |
| 810.3400 | Mosquito, 8lack Fly, and Biting Midge (Sand Fly) Treat m ents | | | | | | |
| 810.3500 | Premises Treatments | | | | | | |
| 810.3600 | Structural Treatments | | | | | | |
| 810.3800 | Methods for Efficacy Testing of Ter m ite Baits | | | | | | |



December 15, 2011

U.S. Bank Government Lockbox 979074 1005 Convention Plaza SL-MO-C2-GL St. Louis, MO 63197

RE: Checks for 2011 PRIA Fees; Virbac AH, Inc. (EPA Co. Number 2382)

Dear Sir or Madam:

Please find enclosed two (2) checks numbered 1013436 and 1013437 made out to the Environmental Protection Agency (EPA) which are both in the amount of \$4,807.00. These checks fulfill the financial obligations in support of two amendments, to be registered under the company Virbac AH, Inc. (EPA Company Number 2382) Also attached for reference are copies of the EPA Form 8570-1 with information on the registration of the two products with EPA.

Should you have any questions about this payment, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

Craig Parks, MS, DVM

Vice President, Research & Development

Virbac Animal Health, Inc.

Commercial/financial information may be entitled to confidential treatment ORDER OF PAY 1013463437SEE OF ******4,807.00 CHECK AMOUNT VOID IF NOT CASHED IN 90 DAYS Four Thousand Eight Hundred Seven Dollars And Zero Cents C/O EXPONENT ATTN: JIM BARRON WASHINGTON, DC 20036 USEPA United States 1150 CONNECTICUT AVE. NW, STE#1100 FT. WORTH, TEXAS 76161 PM (817) 801-5020 P.O. BOX 162059 B/VI IPMORGER CHASE BAGE, B.A. DALLAS, TX 29-534 F13 CENTRALY IN CARROLL DEPORTS THE CHARLES THE 111231AC AH, INC Four Thousand Eight Hundred Seven Dollars And Zero Cents N. Miser しタバオゼ 1150 CONNECTICUT AVE. NW, STE#1100 ระกายระสูง DVIE 02-DEC-11 FIL WORTH, TEXANS 75161 PH. (817) 031-5020 WASHINGTON, DC 20036 VOID IF NOT CASHED IN 90 DAYS # 10 13 t 3 7 # PO. BOX 362059 ATTN: JIM BARRON <u> Дилиовідею зірнативе</u> TORRED GROWING AND Hardon P C/O EXPONENT United States CHECK AMOUNT US DOLLARS *****4,807,00 10134355 OFFICER OFFICER OF > 00

Form Approved OMU No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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| | D _A | ATA MATRIX | | | |
|---|--|-------------------|---|------------|------------------------------|
| Date: December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | Page tof 9 | |
| Applicant's/Registrant's Name & A | Address | | Product: | | |
| Virbac AH, Inc. | | | | | |
| PO Box 162059 | | | EFFIPRO* PLUS TOPICAL SOLUTION FO | R DOGS | |
| Fart Worth TX 76161 Ingredient: Fipronil, Pyriproxyfen | | | | ···· | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Product Chemistry Test Guid | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | THIRID RUMOU | Substitute | Status | 1,000 |
| 830.1550 | Product Identity and Composition | New Submission | Virbac AH, Inc. | OWN | |
| 830.1600 | Description of Materials Used | New Submission | Virbac AH, Inc. | OWN | |
| 830.1620 | Description of Production Process | New Submission | Virbac AH, Inc. | OWN | |
| 830.1650 | Description of Formulation Process | New Submission | Virbac AH, Inc. | OWN | |
| 830.1670 | Description of Formation of Impurities | New Submission | Virbac AH, Inc. | OWN | |
| 830.1700 | 5-Baich Analysis | New Submission | Virbac AH, Inc. | OWN | |
| 830,1750 | Certified Limits | New Submission | Virbac AH. Inc. | OWN | |
| 830.1800 | Analytical Method | New Submission | Virbac AH, Inc. | OWN | |
| 830.6302 | Color | New Submission | Virbac AH, Inc. | OWN | |
| 830.6303 | Physical State | New Submission | Virbac AH, Inc. | OWN | |
| 830,6304 | Odor | New Submission | Virbac AH, Inc. | OWN | |
| 830.6313 | Metal Stability | 11077 01101111355 | Virbac AH, Inc. | NR | |
| 830.6314 | Oxidation/reduction | New Submission | Virbac AH, Inc. | OWN | |
| 830.6315 | Flammability | New Submission | Virbac AH, Inc. | OWN | |
| 830.6316 | Explodability | | Virbac AH, Inc. | NR | |
| 830.6317 | Storage stability | To be conducted | Virbac AH, Inc. | OWN | |
| Signature Lay Kale | | | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 |
| / | | | | | |

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| | $\mathbf{D}A$ | ATA MATRIX | | | |
|---|--|------------------|--|-------------|----------|
| Date December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | Page 2 of 9 | |
| Applicant's/Registrant's Name & Address | | | Product: | | |
| Virbac AH, Inc | | | | | |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUTION FO | OR DOGS | |
| Fort Worth TX 76161 | | | | | <u> </u> |
| Ingrediem: Fipronil, Pyriproxyfen | 1 (C. 2.) - Co N. | MODAL | Calante | 1 000 | T Marin |
| Guideline Reference Number | Gnideline Study Name | MRID Number | Submitter | Status | Note |
| 830.7100 | Viscosity | New Submission | Virbac Al-I, Inc. | OWN | |
| 830.6319 | Miscibility | | Virbac AH, Inc. | NR | |
| 830.6320 | Corrosion characteristics | To be conducted | Virbac AH, Inc. | OWN | |
| 830.6321 | Dielectric breakdown voltage | | Virbac AH, Inc. | NR | |
| 830.7000 | pH | New Submission | Virbac AH, Inc. | OWN | |
| 830.7300 | Density, bulk density, or specific gravity | New Submission | Virhac Al-I, Inc. | OWN | |
| 830.7320 | Particle Size distribution | | Virbac AH, Inc. | NR | 1 |
| 40 CFR 158.340 Toxicology D | ata Requirements | 1 | £ | | |
| 870.1100 | Acute oral toxicity | New Submission | Virbac AH, Inc. | OWN | |
| 870.1200 | Acute dermal toxicity | New Submission | Virbac AH, Inc. | OWN | |
| 870.1300 | Acute inhalation toxicity | Waiver requested | Virbac AH, Inc. | | |
| 870.2400 | Primary eye irritation | New Submission | Virbac AH, Inc. | OWN | |
| 870.2500 | Primary dermal irritation | New Submission | Virbac AH, Inc. | OWN | |
| 870.2600 | Dermal sensitization | New Submission | Virbae AH, Inc. | OWN | |
| Signature | | | Name and Title | | Date |
| 1 1 | | | Craig Parks | | December |
| Cray kah | | | Vice President, Research & Development | | 20, 2011 |
| cay me | | | | | 1 |
| | | | | | 1 |

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| | | DATA MATRIX | | | |
|--------------------------------------|----------------------|----------------|--|--------------|-------------|
| Date: December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | Page 3 of 9 |
| Applicant's/Registrant's Name & A | ddress | | Product: | | |
| Virbac AH, Inc | | | | | |
| PO Box 162059 Fort Worth TX 76161 | | | EFFIFRO® PLUS TOPICAL SOLUTION FO | OR DOGS | |
| Ingredient: Fipronil, Pyriproxyfen | www | | | ············ | <u> </u> |
| Guideline Reference Number | Guideline Study Name | MRID Number | Suhmitter | Status | Nate |
| Efficacy and Safety Data | | | | Çtalas | |
| 870,7200 | Dog safety | 43444905 | Merial | OLD | |
| 870.7200 | Dog safety | 43577711 | Merial | OLD | |
| 870,7200 | Dog safety | 43863802 | Merial | OLD | <u> </u> |
| 870.7200 | Dog safety | 43121110 | Merial | OLD | |
| 870.7200 | Dog safety | 43121111 | Merial | OLD | |
| 370.7200 | Dog safety | 45620507 | Merial | PAY | |
| 870,7200 | Dog safety | 43396408 | Ecto Development Corporation | OLD | |
| 870,7200 | Dog safety | 43612601 | Ecto Development Corporation | OLD | |
| 870.7200 | Dog safety | 44900902 | Virbae AH, Inc. | OWN | |
| 870,7200 | Dog safety | 44900903 | Virbae AH, Inc. | OWN | |
| 870.7200 | Dog safety | 42178309 | Sumitomo Chemical Company, Ltd. | OLD | |
| 870,7200 | Dog safety | New submission | Virbae AH, Inc. | OWN | |
| 810.3300 | Efficacy | 43121114 | Merial | OLD | |
| 810.3300 | Efficacy | 43121115 | Merial | OLD | |
| 810,3300 | Efficacy | 43121116 | Merial | OLD | |
| 810.3300 | Efficacy | 43121117 | Merial | OLD | |
| 810,3300 | Efficacy | 43121118 | Merial | OLD | |
| 810.3300 | Efficacy | 43121119 | Merial | OLD | |
| 810.3300 | Efficacy | 43121120 | Merial | OLD | |
| Signature | | | 1100000 | | Date |
| Craig Rah | | | Craig Parks | | December |
| cay me | | | Vice President, Research & Development | | 1 20, 2011 |

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| | | DATA MATRIX | | | |
|---|----------------------|--|---|--------|------------------------------|
| Date: December 20, 2011 | | | EPA Reg. No./File Symbol 2382-fBA | | Page 4 of 9 |
| Applicant's/Registrant's Name & Address | | | Pruduct: | | |
| Virbae AH, Inc | | | | | |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUTION FOR DOGS | | |
| Fort Worth TX 76161 | | | | | <u></u> |
| Ingrediem: Fipronil, Pyriproxyfen Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| Efficacy and Safety Data | Galdenie Siddy Marie | Wild Number | SIBILITY | Starus | Note |
| | | | | | |
| 810.3300 | Efficacy | 43121121 | Merial | OLD | |
| 810.3300 | Efficacy | 43121122 | Merial | OLD | |
| 810.3300 | Efficacy | 43444901 | Morial | OLD | |
| 810.3300 | Efficacy | 43577701 | Merial | OLD | |
| 810.3300 | Efficacy | 43577712 | Merial | OLD | |
| 810.3300 | Efficacy | 43577713 | Merial | OLD | |
| 810.3300 | Efficacy | 43951701 | Merital | OLD | |
| 810.3300 | Efficacy | 44088901 | Merial | OLD | |
| 810.3300 | Efficacy | 46006002 | Wellmark International | PUBL | |
| 810,3300 | Efficacy | 44900904 | Virbac AH, Inc. | OWN | |
| 810.3300 | Efficacy | 45020601 | Virbac AH, Inc. | OWN | I |
| 810.3300 | Efficacy | Pending; submitted with Effipro Plus Cat Application | | OWN | |
| 810.3300 | Efficacy | New submission | | OWN | |
| Signature Leavy Rah | | | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 |

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| | | DATA MATRIX | | | |
|--|----------------------|-------------|--|--------|------------------------------|
| Date December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | ****** | Page 5 of 9 |
| Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 | | | Product: EFFIPRO* PLUS TOPICAL SOLUTION FOR DOGS | | |
| Fort Worth TX 76161 | | | | | |
| Ingredient: Fipronil, Pyriproxyfen | | | | | |
| Guideline Reference Nomber | Guideline Stody Name | MRID Number | Sobmitter | Status | Note |
| 810.3300 | Efficacy | 44942011 | Merial | PAY | |
| 810.3300 | Efficacy | 44942106 | Merial | PAY | <u> </u> |
| 810,3300 | Efficacy | 45612701 | Merial | PAY | |
| 810.3300 | Efficacy | 45618501 | Merial | PAY | |
| 810.3300 | Efficacy | 45620501 | Merial | PAY | |
| 810.3300 | Efficacy | 45620502 | Merial | PAY | |
| 810.3300 | Efficacy | 45620503 | Merial | PAY | † |
| 810.3300 | Efficacy | 45620504 | Merial | PAY | |
| 810.3300 | Efficacy | 45620505 | Merial | PAY | |
| 810.3300 | Efficacy | 45620506 | Merial | PAY | |
| 810.3300 | Efficacy | 45628101 | Merial | PAY | |
| 810.3300 | Efficacy | 45628102 | Merial | PAY | |
| 810,3300 | Efficacy | 45628103 | Merial | PAY | |
| 810.3300 | Efficacy | 45628104 | Merial | PAY | |
| 810.3300 | Efficacy | 45628105 | Merial | PAY | |
| 810,3300 | Efficacy | 45628201 | Merial | PAY | |
| 810,3300 | Efficacy | 45866901 | Merial | PAY | |
| 810.3300 | Efficacy | 45866902 | Merial | PAY | |
| 810.3300 | Efficacy | 46019201 | Merial | PAY | |
| 810.3300 | Efficacy | 46019202 | Merial | PAY | |
| Signatore Leavy Rah | | | Name and Title Craig Parks Vice President, Research & Developmen | 1 | Date December 20, 2011 |

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| | DAT | A MATRIX | | | |
|---|---|-------------|---|----------|------------------------------|
| Date: December 20 | ······ | | EPA Reg. No./File Symbol 2382-TBA | | Page 6 of 9 |
| Applicant's/Registrant's Name & Address | | | Product: | | |
| Virbac AH, Inc | | | | | 1 |
| PO Box 162059 | | | EFFIPRO® PLUS TOPICAL SOLUTION I | FOR DOGS | |
| Fort Worth TX 7610 | | | | | <u> </u> |
| Ingredient: Fipranil, Guideline | | MRID Number | Submitter | Status | Note |
| Ginderine Reference Number | Guideline Study Name | MRID Number | Shounter | Status | Note |
| Child Resistant F | ackaging | | | | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Child-Resistant Effectiveness | 48095221 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Child-Resistant Effectiveness | 48095222 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Child-Resistant Effectiveness | 48095223 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48095224 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 6 applicators tube test for Schior-Use Effectiveness | 48095225 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 1.34 ml water, 36 applicators tube test for Senior-Use Effectivetess | 48095226 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68ml water, 1 applicator tube test for Child-Resistant Effectiveness | 48095227 | Virbae AH, Inc. | OWN | |
| Signatore Long to | | | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 |

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| | DATA | MATRIX | | | |
|---|---|---|---|---------|------------------------------|
| Date: December 16, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | |
| Applicant's/Registrant's Name & Address | | | Product: | | |
| Virbac AH, Inc PO Box 162059 Fort Worth TX 7616 | ı | | EFFIPRO [®] PLUS TOPICAL SOLUTION F | OR DOGS | |
| Ingredient: Pipronil, | | | | _ | 1 |
| Guideline Reference Number | Guideline Stody Name | MRID Number | Subnuiter | Status | Note |
| 40 CFR 157 | Evaluation of the 3 mtl Applicator Tube with 2.68 ml water, 6 applicators tube test for Child-Resistant Effectiveness | 48095228 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Child-Resistant Effectiveness | 48095229 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48095230 | Virbac Al-I, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 6 applicators tube test for Senior-Use Effectiveness | 48095231 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3 ml Applicator Tube with 2.68 ml water, 36 applicators tube test for Scnior-Use Effectiveness | 48095232 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 1 applicator tube test for Child-Resistant Effectiveness | 48095233 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6 inl Applicator Tube with 4.02 ml water, 6 applicators tube test for Child-Resistant Effectiveness | 48095234 | Virbac AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6 ml Applicator Tube with 4.02 ml water, 36 applicators tube test for Child-Resistant Effectiveness | 48095235 | Virbac AH, Inc. | OWN | |
| Signature Lay Lah | | *************************************** | Name and Title Craig Parks Vice President, Research & Development | | Date December 20, 2011 |

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| | DAT | 'A MATRIX | | | |
|---------------------------------------|--|-------------|---------------------------------------|------------|-------------|
| Date: December 20, 2011 | | | EPA Reg. No./File Symbol 2382-TBA | | |
| Applicam's/Registram's Name & Address | | | Product: | | Page 8 of?) |
| Virbac AH, Inc | | | FV-10. | | |
| PO Box 162059 Fort Worth TX 76161 | | | EFFIPRO* PLUS TOPICAL SOLUTION | N FOR DOGS | |
| Ingrediem: Fipronil, | · | | | | |
| Guideline | Guideline Study Name | MRIO Number | Submitter | Status | Note |
| Reference Number | | | | | 1,1,0,10 |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 1 | 48410001 | Virbac AH, Inc. | OWN | |
| | applicator tube test for Child-Resistant Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 1 | 48410002 | Virbae AH, Inc. | OWN | |
| | applicator tube test for Senior-Use Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 6 | 48410003 | Virbac AH, Inc. | OWN | |
| | applicator tube test for Child-Resistant Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the Iml applicator tube with 0.67 ml water, 6 | 48410004 | Virbac AH, Inc. | OWN | |
| | applicator tube test for Senior-Use Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 36 | 48410005 | Virbac AH, Inc. | OWN | Ì |
| | applicator tube test for Child-Resistant Effectiveness | | | | 1 |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 36 | 48410006 | Virbae AH, Inc. | OWN | |
| | applicator tube test for Senior-Use Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 1ml applicator tabe with 0.67 ml water, 3 | 48410007 | Virbae AH, Inc. | OWN | |
| | applicator tube test for Child-Resistant Effectiveness | | | | <u> </u> |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 0.67 ml water, 3 | 48410008 | Virbac Al-I, Inc. | OWN | |
| | applicator tube test for Senior-Use Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 1.34 ml water, 3 | 48410009 | Virbae AH, Inc. | OWN | |
| | applicator tube test for Child-Resistant Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 1.34 ml water, 3 | 48410010 | Virbac AH, Inc. | OWN | |
| | applicator tube test for Senior-Use Effectiveness | | | | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 3 | 48410011 | Virbac AH, Inc. | OWN | |
| | applicator tube test for Child-Resistant Effectiveness | | | | |
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| 1.21 | | | Craig Parks | | December |
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| Date December 20, 2 | | | EPA Reg. Na./File Symbol 2382-TBA | \ | Page 9 of 9 |
| | nt's Name & Address | | Product: | | |
| Virbac AH, Inc PO Box 162059 Fon Wonh TX 7616 | 1 | | EFFIPRO® PLUS TOPICAL SOLUTI | ON FOR DOGS | |
| Ingredient: Fipronil, | | | | | <u></u> |
| Guideline Reference Number | Gnideline Study Name | MRID Number | Submitter | Status | Note |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 3 applicator tube test for Senior-Use Effectiveness | 48410012 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 4.02 ml water, 3 applicator tube test for Child-Resistant Effectiveness | 48410013 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 1ml applicator tube with 4,02 ml water, 3 applicator (Bbe test for Senior-Use Effectiveness | 48410014 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 1 applicator tube test for Senior-Use Effectiveness | 48410015 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 3ml applicator tube with 2.68 ml water, 36 applicator tube test for Senior-Use Effectiveness | 48410016 | Virbae AH, Inc. | OWN | |
| 40 CFR 157 | Evaluation of the 6ml applicator tube with 4,02 ml water, 6 applicator tabe test for Senior-Use Effectiveness | 48410017 | Virbac AH, Inc. | OWN | |
| Signature Long Kah | | | Name and Title Craig Parks Vice President, Research & Developm | ent | Date December 20, 2011 |

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| Date: December 20, 2011 | | EPA Reg. No./File Symbol 2382-TBA | | Page 1 of 9 |
| Applicant's/Registrant's Name & Address | | Product: | | |
| Virbae AH, Inc. | | | | |
| O Box 162059 | | EFF#RO* PLUS TOPICAL SOLUTION FO | R DOGS | |
| Fort Worth TX 76161 | | | | <u> </u> |
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| Fort Worth TX 76161 Ingredient: Fipronil, Pyriproxyfen | EPA Reg. No./File Symbol 2382-TBA Product: EFFIPRO* PLUS TOPICAL SOLUTION FO Submitter Virbae AH, Inc. Virbae AH, Itte | R DOGS Status OWN | Page 7 of 9 Note |
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| Virbac Al-I, inc PO Box 162059 Fort Worth TX 76161 Ingrelient: Fipronii, Pyriproxyfen Guideline Guideline Study Name Reference Number MRID Number | EFFIPRO* PLUS TOPICAL SOLUTION FO Submitter Virbae AH, Inc. | Stahis | Note |
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| Date: August 23, 2011 | | | EPA Reg Na./File Symbol 87825-R | | Page 1 of 6 |
| Applicant's/Registrant's Name & A | ddress | *************************************** | Product: Fipronil Technical | *************************************** | |
| Virbac SA | | | | | |
| F-06516 Carros, France | | | | | |
| Ingredient: Pipronil | | | | | <u> </u> |
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| 830.1550 | Product Identity and Composition | 48095240, 48449201 | Virbae. | OWN | |
| 830.1600 | Description of Materials Used | 48095240 | Virbac | OWN | |
| 830.1620 | Description of Production Process | 48095239 | Virbac | OWN | |
| 830.1650 | Description of Formulation Process | 48095239 | Virbac | OWN | |
| 830.1670 | Description of Formation of Impurities | 48095240, 48449201 | Virbac | OWN | |
| 830.1700 | Proliminary Analysis | 48095241 | Virbae | OWN | |
| 830.1750 | Certified Limits | 48095240, 48449201 | Virbac | OWN | |
| 830.1800 | Analytical Method | 48095242 | Virbae | OWN | |
| 830.1900 | Submittal of samples | | Virbac | N/A | |
| 830.6302 | Color | 48095240, 48095243 | Virbac | OWN | |
| 830,6303 | Physical State | 48095240, 48095243 | Virbae | OWN | |
| 830.6304 | Odor | 48095243 | Virbae | OWN | |
| 830.6313 | Accelerated Storage Stability-Metal Ions | 48095243 | Virbac | OWN | |
| 830.6314 | Oxidation/reduction | 48095239 | Virbac | OWN | |
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| Date August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | | Page 2 of 6 |
| Applicant's/Registrant's Name & Address Virbac SA I ere avenue 2065 M - LID F-06516 Carros, France | | | Product: Fipronil Technical | | |
| Ingredient: Fipronil | | · | | ****** | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 830.6318 | Viscosity | | Virbac | N/A | |
| 830.6319 | Miscibility | | Virbae | N/A | Solid |
| 830.6320 | Corrosion characteristics | | Virbae | OWN | See note page 2 |
| 830.6321 | Dielectric breakdown voltage | | Virbuc | N/A | Waived |
| 830.7000 | рН | 48095247 | Virbae | OWN | |
| 830.7200 | Melting Point | 48095249 | Virbac | OWN | |
| 830.7300 | Density bulk density or specific gravity | 48095250 | Virbac | OWN | |
| 830.7320 | Particle Size | | Virhac | N/A | |
| 830.7050 | UV/Visible Spectrum | 48095248 | Virbac | OWN | |
| 830.7370 | Dissociation constant | 48095251 | Virbac | OWN | |
| 830.7520;830.7550; 830.7560 830.7570 | Octanol/water partition coefficient | 48095244 | Virbae | OWN | |
| 830.7840;830.7860 | Solubility | 48095245 | Virbac | OWN | |
| 830.7950 | Vapor pressure | 48095246 | Virbac | OWN | |
| Signature | - Droberta | | Name and Title Jean-Pascal Marc Corporate Product Innovation Director | | Date August 23, 2011 |

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Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.

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| Date: August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | | Page 3 of 6 |
| Applicant's/Registrant's Name & A Virbac SA Tere avenue 2065 M - LID F-D6516 Carros, France | Address | | Product: Fipronil Technical | | |
| Ingredient: Fipronil | | | | | |
| Guideline Reference Number | Guideline Snidy Name | MRID Number | Submitter | Status | Note |
| 40 CFR 158.340 Toxicology D | | ************** | 2.02 | | |
| 870.1100 | Acute oral toxicity | 42918628; 43235401 43279706 | BASF | OLD | |
| 870.1200 | Acute dermal toxicity | 42918629 | BASF | OLD | |
| 870.1200 | Acute ilermal toxicity | 43235402 | BASF | QLD | |
| 870.1300 | Acute inhalation toxicity | 42918631 | BASF | OLD | |
| 870.2400 | Primary eye irritation | 42918632 | BASF | OLD | |
| 870.2500 | Primary dormal irritation | 42918630 | BASF | OLD | |
| 870.2600 | Dermal sensitization | 42918634 | BASF | OLD | |
| 870.6100 | Acute delayed neurotoxicity | 42918635 | BASF | QLD | |
| 870.6100 | Acute delayed neurotoxicity | 43559501 | BASF | OLD | |
| 870.3100 | 90-day oral toxicity – rodent | 42918643 | BASF | OLD | |
| 870.3150 | 90-day oral toxicity - nonrodent | 42918642 | BASF | OLD | |
| 870.3200 | 21-day dermal toxicity | 42918644 | BASF | OLD | |
| 870.3250 | 90-day dermal toxicity | DATA GAP | BASF | GAP | *See below |
| 870.6100 | 90-day (curotoxicity - mammal | 43291703 | BASF | OLD | |
| 81-8 | Neurotoxicity to Rats by Acute Oral Adutinistration | 44431801 | BASF | PAY | |
| Signature | | | Name and Title Jean-Pascal Marc | | Date August 23, 2011 |

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| Date August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | | Page 4 of 6 |
| Applicam's/Registrant's Name & Address Virbae SA Fere avecue 2065 M - LID | | | Product: Fipronil Technical | | |
| F-06516 Carros, France Ingredient: Fipronil | | | | | |
| Guideline Reference Number | Guideline Shidy Name | MRID Number | Submitter | Status | Note |
| | Pata Requirements (Continued) | | | | |
| 84-2 | Structural chromosomal aberration | 42918680 | BASF | OLD | |
| 84-2 | Structural chromosomal aberration | 42918653 | BASF | OLD | - |
| 84-2 | Other genotoxic effects | 42918651;42918653 43501703 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42918655 | BASF | OLD | <u> </u> |
| 85-1/870.7485 | General metabolism | 43253701 | BASF | PAY | |
| 85-1/870.7485 | General metabolism | 43737308 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42918654 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 42977904 | BASF | OLD | |
| 85-1/870.7485 | General metabolism | 43253701 | BASF | OLD | |
| 85-2/870.7600 | Dermal penetration | 43737308 | BASF | PAY | |
| 85-7/870.7600 | Imminotoxicity | DATA GAP | | GAP | *See below |
| 40 CFR 158.490 Wildlife and | Aquatic Organisms Data Requirements | | | OLD | |
| 71-1/850.2100 | Avian oral LD 50 – mallant or bobwhite | 42918617 42918616 | BASF | OLD | |
| 72-1/850.1075 | Freshwater fish LC 50 – rainbow of blnegill | 42918624;42918673; 42918674;42977902 43279703;43291718 | BASF | OLD OLD OLD | |
| Signature | | • | Name and Title Jean-Pascal Mare Corporate Product Innovation Director | 7 | Date August 23, 2011 |

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| Date: August 23, 2011 | | | EPA Reg. No./File Symbol 87825-R | | Page 5 of 6 |
| Virbac SA | | | Product: Fipronil Teclmical | | |
| tere avenue 2065 M - LID | | | | | |
| F-06516 Carros, France | | | | | |
| Ingredient: Fipronil Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | 1 | T X |
| 83-1/870,4100 | Chronic feeding – rodent | 42918648 | BASF | Status | Note |
| 83-1/870.4100 | | | ****** | OLD | |
| 83-1/8/0.4100 | Chronic feeding - nonrodent | 42918645 | BASF | OLD | |
| 83-1/870.4100 | Chronic feeding - nonrodent | 43402802 | BASF | PAY | |
| 83-2/870.4200 | Oncogenicity – mouse | 42918649 | BASF | OLD | |
| 83-2/870.4200 | Oncogenicity - mouse | 43501702 | BASF | PAY | |
| 83-2/870.4200 | Oncogenicity – rat | 42918648 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity – rabbit | 42918646 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rat | 42977903 | BASF | OLD | |
| 83-3/870.3700 | Teratogenicity - rat | 44275001 | BASF | PAY | |
| 83-6/870.6300 | Developmental negrotoxicity | 44039002 | BASF | PAY | · |
| 83-4/870.3800 | Reproduction | 42918647 | BASF | OLD | |
| 84-2/870,5100 | Gene inutation | 42918652 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 42918679 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291716 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291717 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291721 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43291722 | BASF | OLD | |
| 84-2/870.5100 | Gene mutation | 43401102 | BASF | OLD | |
| Signature | | | Name and Title Jean-Pascal Marc Corporate Product Innovation Dire | ****** | Date August 23, 2011 |

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| Date: August 23, 2011 | | | El ^s A Reg. No./File Symbol 87825-R | | Page 6 of 6 |
| Applicant's/Registrant's Name & Address Virbac SA | | | Product: Fipronil Technical | | |
| Tere avenue 2065 M - LID | | | | | |
| F-06516 Carros, France | | | | | |
| Ingredient: Fipronil | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 72-2/850.1010 | Acute LC 50 freshwater invertebrates (Daphnia magna) | 42918625 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daphuia magna) | 42918669 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daphyia magna) | 42918671 | BASF | OLD | |
| | Acute LC 50 freshwater invertebrates (Daphuia magua) | 43291719 | BASF | OLD | |
| 835.2110 | Hydrolysis | 42977905 | BASF | OLD | |
| 40 CFR 158.390 Reentry Protection Data Requirements | | | | | |
| 133-3 | Dermal exposure - Fipronil | 44433302 | Merial | PAY | T |
| 133-4 | Inhalation exposure - Fipronti | 44433302 | Merial | PAY | |
| 132-1 | Dislodgeable residue dissipation - Fipronil | 44531203 | Merial | PAY | - |
| N/A | Dermal and inhalation exposure of commercial pet groomers (Spot) - Fipronil | 44433303 | Merial | PAY | |
| N/A | Analytical method for exposure studies - Fipronil | 44433308 | Merial | PAY | |
| Signature | | ···· | Name and Tille | • | August 23. |
| S. Carrier and Car | المراجعين | | Jeant-Pascal Mare | | 2011 |
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^{*} Pursuant to 40 CFR 152.96 (c), Virbac hereby certifies that Virbae has no basis to believe that this requirement is not a data gap and, further, that Virbae has sent by certified mail to all cumpanies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbae will update the Agency us to the information, if any, Virbae receives in response to this "data gap" letter.



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| Date: August 23, 2011 | | | EPA Reg No./File Symbol 87825-R | ******* | Page 1 of 6 |
| Applicant's/Registrant's Name & Advirbac SA lere avenue 2065 M - LID | dress | | Product: Fipronil Teclinical | | |
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| Signature | Al man | | Name and Title Jean-Pascal Marc Corporate Product Innovation Director | er . | Date August 23, 2011 |

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| Date August 23, 2011 Applicant's/Registrant's Name & Add Virbac SA lere avenue 2065 M - LID F-06516 Carros, France Ingredient: Fipronil | | | EPA Reg No./File Symbul 87825-R Product: Fipronil Technical | | Page 2 of 6 |
| Guideline Reference Number | Guiddine Sandy Name | MRID Number | Submitter | Status | Note |
| Analy in 1994 | A CONTRACTOR OF THE SECOND STATE OF THE SECOND | | Virbac | N/A | |
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Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbae has initiated these studies and will submit the final reports if required when the studies are completed.

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| Date: August 23, 2011 | | EPA Reg No./File Symbol 8782 | 5-R | Page 3 of 6 |
| Applicant's/Registrant's Name & Address Virbae SA | | Product: Fipronil Technical | - | |
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| F-06516 Carros, France | | | | <u> </u> |
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| 40 CFR 158.340 Toxicology Data Requirements | | | | |
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| J. Janes | | Jean-Pascal Marc Corporate Product Innovatio | it Director | August 23, 2011 |

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| Virbac SA Tere avenue 2065 M - LID F-06516 Carros, France | | | Product: Fipronil Technical | | |
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| Date: August 23, 2011 | | | EPA Reg. No./File Symbol 87825-R | | Page 6 of 6 |
| Applicant's/Registrant's Name & A | Address | | Product: Fipronil Technical | | |
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^{*} Pursuant to 40 CFR 152.96 (c), Virbae hereby certifies that Virbae has no basis to believe that this requirement is not a data gap and, forther, that Virbae has sent by certified muil to all cumpanies on the corrent EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbae will update the Agency as to the information, if any, Virbae receives in response to this "data gap" letter.

